AMENDED EXHIBIT E

Part 2

Page 288 Page 286 It includes this Establishment Inspection Report. 1 Digitek?") 1 2 So the Establishment Inspection Report VIDEO OPERATOR: We're now back on the 2 that I base my opinion on was available to them at the 3 3 videotape. 4 time they rendered that opinion and they are This is the start of Tape 6. 4 5 differing. They are saying it doesn't impact Digitek. 5 The time is 5:15 p.m. 6 I am making a generalization of saying THE WITNESS: Okay. I do not know what 6 7 these defective systems may have impacted signal evidence the FDA considered in reaching the opinion 7 detection because there's a lot of evidence that these that there was no risk to public health, whether that 8 8 9 things weren't done. 9 was only based on the evidence in the AERS database 10 The FDA inspectors are concerned with and the probability of this being a high-frequency 10 11 Health Hazard Assessments that aren't done in 11 event with pills on the market. There was enough concern to draw the 12 realtime. 12 There's concern that there's still lack 13 pills from the market. I have no idea whether it was 13 of single-case reporting, which means the FDA may or 14 one pill, a hundred. There is no, at this point. But 14 15 may not have seen them all. They're saying at this you have to rely that there was some sort of an FDA 15 16 point, based on what they know, this is okay. 16 analysis. 17 You're presenting me with evidence that 17 Whether or not it includes the 18 may, indeed, negate my opinion. remediation plan or an assessment of the system that 18 19 And I'm starting to feel more 19 produced the data, I don't know the answer to that. comfortable now with the process of being a witness in 20 20 deposition that I am to modify my position truthfully 21 21 **EXAMINATION** based on new evidence, that this is what I've been 22 22 BY MR. KAPLAN: 23 hired to do. You have a high degree of confidence in 23 If I had had all of this, my opinions 24 24 the FDA? would probably have been more specific, definitely 25 25 A. Yes. If ---Page 289 Page 287 more defensible on deposition. But they would not And you don't believe that the FDA would 1 1 2 have been subject to this new information. 2 make such a statement lightly, do you? 3 And I'm trying to couch my response to 3 My opinion is that they felt these you to give diligence to all parties in the attempt to 4 remediation processes were so serious that there could 4 5 handle this situation in realtime with the deadline be a bunch of cases in the Actavis database 5 6 correctly. I don't want to be seen as accusing the 6 unreported, they would have gone in and looked. 7 They would have pulled up the coded Miller firm or Motley Rice. 7 I think there was issues with how the 8 8 cases and text search. data was gathered in discovery and maybe disseminated. 9 9 Because my understanding, based upon There may be the opinion that the 10 10 only on verbal communications, the kind of, you know, discovery was completely adequate on this case or my 11 11 afternoon coffee conversations, is that those are the request for further information may have been 12 kind of things they do when they have a market 12 honored. But I was told to try to come to truth based 13 13 withdrawal. But I do not know if that is standard in on the evidence that I was provided. 14 14 So the evidence that you've provided to 15 15 a recall of generic drugs. me is that the FDA may have completely overruled my 16 16 I can't comment on the adequacy of their 17 opinion, and that based on their knowledge of response. And I don't know whether it was done or 17 compliance and the adequacy of the single-case reports 18 18 not. that still led me to say there could be vulnerability, 19 19 O. All right. these are defective processes, the FDA was willing to 20 20 But the idea that they issued a release A. 21 admit that statement. and they left it out on the web site unmodified means 21 And the strength of the FDA and their 22 22 at this point they don't believe there's a risk. 23 access to information I don't have can completely 23 That's their position. negate my opinion based on these -- this subset of 24 24 The FDA is maintaining their position

evidence.

25

25

based upon present data. I do not know what that is.

Videotaped

June 30, 2010

1 2	Page 290		Page 292
	MR. KAPLAN: Thank you.	1	That would be an even greater
_	MR. THOMPSON: I don't have anything	2	embarrassment.
3	else.	3	But at this point with what you're
4	MR. KAPLAN: I appreciate your candor.	4	presenting me on the assumption that that FDA
5	I appreciate you	5	statement is backed by evidence and data, data that
6	THE WITNESS: I was asked how to handle	6	was generated by these inadequate systems, by
7	this. I was told to try to seek truth.	7	voluntary reporting with an old drug, I believe a
8	MR. KAPLAN: And that's what we're	8	federal judge would discard my expert opinion in light
9	trying to seek here.	9	of a stronger expert opinion.
10	THE WITNESS: And I just I want to be	10	MR. KAPLAN: Thank you very much for
11	certain the fact that I still don't have all the	11	your candor.
12	information, that what the FDA had really is	12	THE WITNESS: That my what I want
13	sufficient to overturn mine. That's the question at	13	to make sure is my response is appropriate because I
14	hand here.	14	don't help anybody.
15	And if there is any other question of	15	MR. THOMPSON: Let's just wait until
16	the adequacy of that of the information on the FDA	16	there's a question on the table. Okay?
17	statement, if they if they did not have sort of	17	THE WITNESS: I'm sorry.
18	this linear timeline that I have, then there probably	18	BY MR. KAPLAN:
19	should be more expert witness testimony.	19	Q. Go ahead. I didn't want to interrupt
20	Perhaps I should be replaced by someone	20	you. Go ahead.
21	stronger.	21	A. No. My main concern in taking this
22	But if we have found that this FDA	22	assignment was that I was adequately prepared by
23	evidence will, in October, in front of a panel of	23	experience and seniority to be truly an expert
24	federal judges, lead to the same conclusion, is there	24	witness. I did not realize the magnitude of the case.
25	any value with my sitting there and coming up with the	25	If you're going to start to do new work,
	Page 291		Page 293
1	same conclusion?	1	it is generally advisable to do it in a circumscribed
2	I think the evidence issue is still	2	setting where there is no question of one's adequacy
3	open. But it appears that if we're making the	3	for the magnitude of the litigation.
. 4	assumptions that the FDA had all of this evidence and	4	If there's any question of that with me,
5	they will overrule this, this situation will probably	5	I would have liked to have known it because I would
	repeat itself in October.		
6		6	not have proceeded.
6 7	And right now, I have to be very careful	6 7	not have proceeded. Now, that being said, I was asked to
	because I can't think of a way to rebut your	1	not have proceeded. Now, that being said, I was asked to render opinion in a short time frame based on a given
7		7 8 9	not have proceeded. Now, that being said, I was asked to render opinion in a short time frame based on a given amount of evidence, and I asked for further evidence
7 8	because I can't think of a way to rebut your	7 8. 9 10	not have proceeded. Now, that being said, I was asked to render opinion in a short time frame based on a given amount of evidence, and I asked for further evidence and I reviewed what was provided.
7 8 9 10 11	because I can't think of a way to rebut your presenting me with the FDA looked at this and came up with a different conclusion and they had the evidence you didn't have.	7 8 9 10 11	not have proceeded. Now, that being said, I was asked to render opinion in a short time frame based on a given amount of evidence, and I asked for further evidence and I reviewed what was provided. I did not pull in some of the statements
7 8 9 10 11 12	because I can't think of a way to rebut your presenting me with the FDA looked at this and came up with a different conclusion and they had the evidence you didn't have. I can't immediately contradict that.	7 8 9 10 11 12	not have proceeded. Now, that being said, I was asked to render opinion in a short time frame based on a given amount of evidence, and I asked for further evidence and I reviewed what was provided. I did not pull in some of the statements from the depositions. That was a deliberate
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7 8 9 10 11 12 13 14 15 16 17	because I can't think of a way to rebut your presenting me with the FDA looked at this and came up with a different conclusion and they had the evidence you didn't have. I can't immediately contradict that. BY MR. KAPLAN: Q. Nor would you want to, would you? A. Not if it's foolish and untrue. Q. And you believe in the FDA? You believe they told the truth?	7 8 9 10 11 12 13 14 15 16	not have proceeded. Now, that being said, I was asked to render opinion in a short time frame based on a given amount of evidence, and I asked for further evidence and I reviewed what was provided. I did not pull in some of the statements from the depositions. That was a deliberate statement, not to comment on the personnel in the depositions, but to stick with the evidence from the FDA. But at this point, I have been told I was adequate to do this job. The point to do it was
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7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	because I can't think of a way to rebut your presenting me with the FDA looked at this and came up with a different conclusion and they had the evidence you didn't have. I can't immediately contradict that. BY MR. KAPLAN: Q. Nor would you want to, would you? A. Not if it's foolish and untrue. Q. And you believe in the FDA? You believe they told the truth? They're telling the truth; right? A. Yes. I don't know whether there's potentially other information they did not have. I'd hate to be embarrassed by people him replacing me with another expert witness and more	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	not have proceeded. Now, that being said, I was asked to render opinion in a short time frame based on a given amount of evidence, and I asked for further evidence and I reviewed what was provided. I did not pull in some of the statements from the depositions. That was a deliberate statement, not to comment on the personnel in the depositions, but to stick with the evidence from the FDA. But at this point, I have been told I was adequate to do this job. The point to do it was to seek truth based on the evidence. And I had nothing to worry about with anybody accusing me of wrongdoing, either by going into something where I was not adequately prepared or or otherwise.
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7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	because I can't think of a way to rebut your presenting me with the FDA looked at this and came up with a different conclusion and they had the evidence you didn't have. I can't immediately contradict that. BY MR. KAPLAN: Q. Nor would you want to, would you? A. Not if it's foolish and untrue. Q. And you believe in the FDA? You believe they told the truth? They're telling the truth; right? A. Yes. I don't know whether there's potentially other information they did not have. I'd hate to be embarrassed by people him replacing me with another expert witness and more	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	not have proceeded. Now, that being said, I was asked to render opinion in a short time frame based on a given amount of evidence, and I asked for further evidence and I reviewed what was provided. I did not pull in some of the statements from the depositions. That was a deliberate statement, not to comment on the personnel in the depositions, but to stick with the evidence from the FDA. But at this point, I have been told I was adequate to do this job. The point to do it was to seek truth based on the evidence. And I had nothing to worry about with anybody accusing me of wrongdoing, either by going into something where I was not adequately prepared or or otherwise.

Videotaped

June 30, 2010

Page 296 Page 294 the probability is that that would be confirmed by 1 in this case. That -- I leave that up to you, really. 1 MR. THOMPSON: Thank you. 2 these federal judges on October 8th, then we have hit 2 THE WITNESS: I don't -- I'm talking too 3 3 truth. much. 4 4 We have hit an expert witness that is MR. THOMPSON: Thank you. stronger than I am who has seen all of the data. We 5 5 Dick, I think you've got some questions. need to be sure they've seen all of the data. 6 6 7 BY MR. KAPLAN: 7 But for me to go in with the Well, if you have anything else that you 8 inexperience in expert witness, a report based on a 8 want to say, anything, you know, this is your 9 sampling of data that may need to be modified and 9 opportunity to go ahead and make any statements you revisions may not serve anyone. And there may be --10 10 MR. THOMPSON: Doctor, you have said want to make. 11 11 Well, my concern in doing something new this many times. 12 A. 12 was to not -- I don't want to put the integrity of the THE WITNESS: I'm sorry. 13 13 litigation in jeopardy either way because of my 14 MR. THOMPSON: I think we're -- I think 14 15 inexperience. we've got it. 15 And so my going into a court as a 16 THE WITNESS: I'm more worried about me. 16 lightweight does not serve these people. The question And I wanted --17 17 is, am I? But that's their decision. 18 18 MR. THOMPSON: That's a given. It's very clear right now that there's a THE WITNESS: Yes. 19 19 certain -- that I am being entrained by whoever's 20 20 BY MR. KAPLAN: questioning me. You want to be vindicated. You want to 21 21 O. And my concern not to do anything wrong 22 22 go out with a -and vindicate myself, that may or may not be evidence 23 23 I want to be vindicated. of my inexperience with -- if I was a really heavy-24 24 Q. -- good feeling that you've arrived at weight expert witness, I might hit back. I'm not 25 25 the truth? Page 297 Page 295 Yes. But these people offered me the 1 ready right now to hit back. 1 But I'm very concerned by the fact that 2 opportunity to do something new and they trusted me to 2 you're showing me evidence the FDA looked at this and 3 act on their behalf to really look at this. And under 3 said there's no risk to public health and that there 4 no way do I want to malign them or do them wrong. 4 5 was a Congressional inquiry. 5 But what we're seeing is the process of discovery was more extensive than we realized. There So there was a -- this is already, you 6 6 know, under a lot of scrutiny and has a high degree of 7 7 may be more. certainty. I have to modify my opinion. But it looks like I was overruled by the 8 8 MR. KAPLAN: Thank you very much. 9 FDA. And it would be foolish for me to go into a 9 Thank you so much for your candor. Federal Court and challenge that. There are people 10 10 **EXAMINATION** 11 who do that. 11 BY MR. DEAN: 12 But you're not one of them? 12 O. O. I just have a few questions, but they're 13 13 A. I know attorneys who do that. medical questions, they're factual questions. I want 14 14 O. You're not one of them? to -- I'd ask that you listen to the question. I It may be some day. But I think at this 15 15 think you'll be able to give short answers. 16 point in time, that I'm probably not the person to be 16 17 They arise from a question that doing that. That's my honest opinion. 17 Mr. Thompson asked you or at least an answer that you 18 18 There are people that might be able to gave to one of Mr. Thompson's questions. 19 say to me tomorrow, Karen, we want you to do that. 19 And that was about the information that 20 20 But I don't support the kind of litigation where went into gathering MedWatch reports in hard cases, in 21 people go in and challenge the FDA. I don't think I 21 cases involving digitalis. 22 22 would have taken that. So my question to you is this: Would 23 23 I know it's done. I know it's done you agree that people who are taking Digitek -- strike 24 successfully. And the people that do it, I agree with 24 how they did it. I don't know that I should do that 25 25

Videotaped

June 30, 2010

Page 298 Page 300 of those issues, even in conversations over lunch or 1 1 Would you agree that people who are not 2 2 taking Digitek, who have been prescribed it for an dinner, casual conversations. underlying heart condition, that they can have higher 3 I avoid, for the most part, commenting 3 4 on some of these high-profile cases. than normal levels with perfectly acceptable normal 5 I do know that some of these pro --5 tablets? 6 high-profile cases that have used that argument have 6 Yes. Digitalis toxicity is well A. 7 been forced to settle. I cannot tell you --7 documented to occur with no concomitant abnormality in 8 8 Q. Let me -- excuse me. 9 A. -- that I know --9 And it can occur for a variety of Q. 10 Q. I'm not asking you about other cases. 10 medical reasons, such as renal failure, which develops This is the only case involving Digitek that I'm aware 11 or gets worse than it was in the past; correct? 11 12 of. I don't know what other high-profile cases you're 12 Yes. Intercurrent events, such as renal 13 13 talking about. failure, can precipitate digitalis toxicity. 14 All of us would like to get out of here 14 And a number of other medical events can also lead to digitalis toxicity on perfectly normal 15 in the not too distant future. My question was a very 15 16 focused question. 16 tablets; agreed? Yes. 17 Are you aware of a recognized scientific 17 A. methodology by which a safety signal could be arrived 18 18 Q. And does -- and so what I was leading up 19 at to ascertain the defective Digitek was on the to, doesn't that make it extraordinarily difficult to 19 market given the inherent difficulties we've spoken 20 20 recognize through a safety signal analysis whether 21 there is a -- safety signal is throwing off or is 21 about here in the last few minutes? 22 There is a -- boy, this is -- I have to giving a signal of a defective tablet? 22 say this right. There is a significant possibility. 23 23 Yes. The statement from the consumer I was going to say high likelihood. I don't know how group makes the point that -- I don't know whether we 24 24 25 to express this. But the lower the event rate, the 25 should cite it verbatim, but it's very, very difficult Page 299 Page 301 1 harder it is to demonstrate. 1 to list causality to the Digitek tablets to any given 2 For example, it's very difficult in 2 pesticides to show differences in cancer rates for 3 3 And I made a note in the margin that at 4 very, very low event rate cancers. 4 this point I have no evidence to refute that 5 The lower the event rate, the harder it 5 statement. 6 is to find a vigorous scientific method to demonstrate 6 And I found when I looked up the drug it and the larger the sample size you need to 7 7 label, I told you I did go on the Internet, that it 8 8 confirmed that digitalis toxicity, clinical digitalis 9 It's -- there's increasing evidence that 9 toxicity, can be seen at normal -- normal therapeutic this is a very, very low frequency event. But there's 10 10 levels. 11 a paucity of real hard evidence on what was the event 11 So the person does not -- this is rate. That's where I started asking these questions. 12 12 extremely complicated. The FDA has sort of confirmed that it's 13 However, one more thing, what I'm saying 13 a low event rate. Based on that, it becomes right now is technically outside of the scope of my 14 14 increasingly difficult to scientifically demonstrate 15 15 review. in any given case. And that's what the consumer group 16 16 Q. Doesn't that make -- doesn't the fact, 17 though, that you just articulated from the consumer 17 And right now, I don't have the 18 group and the fact that you -- the facts that you've 18 19 information and I probably don't have the expertise to testified to a few minutes ago that you can have high 19 refute that. You need somebody who carries a Ph.D. in 20 20 levels with normal tablets, doesn't that make it 21 impossible to apply any recognized scientific 21 epidemiology. As we sit here today, you cannot cite to 22 methodology to look at adverse events on Digitek and 22 me a recognized scientific methodology by which one 23 23 conclude they were due to a tablet defect? could discern a safety signal for defective Digitek 24 I know that this argument has been used 24 25 from looking at a set of medical records, can you? 25 in prior litigation. I have specifically stayed out

Videotaped

June 30, 2010

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Page 304
                                              Page 302
                                                                     to be able to say whatever you want to say because
              That's a very focused question. Can you
                                                                1
 1
      cite me a recognized scientific methodology by which
                                                                     this is your last opportunity to do so, maybe. It's
                                                                2
 2
                                                                     your testimony under oath.
                                                                3
 3
      that can be done?
                                                                             So if there's any other statement you
 4
         A. I know the methodologies. I am not
                                                                4
                                                                     want to make or any concern you want to express --
      expert enough to render an opinion on their scientific
                                                                5
 5
      validity for the low frequency events of the Digitek
                                                                6
                                                                              I want assurance that my insecurity
 6
                                                                     because I'm new to this expert witness game has not
                                                                7
 7
      tablets.
                                                                     led me to abandon an opinion and fail my client.
                                                                8
 8
         Q.
               Thank you.
                                                                             But I have difficulty arguing with that
                                                                9
 9
         A.
               I know them generally for doing adverse
                                                                     statement of the FDA, if it's based on the data that I
10
      event rates. I cannot comment on their implementation
                                                              10
                                                                     wanted to see, because I'm afraid there are other
                                                              11
      in this particular case.
11
                                                              12
                                                                     people that would weigh the FDA more than me.
              MR. DEAN: Thank you.
12
                                                                              I just want you to understand this.
                                                              13
              I have no further questions.
13
                                                                     This is not an expert witness game.
                                                              14
                  EXAMINATION
14
                                                                        A.
                                                                              Oh, I know this.
                                                              15
      BY MR. KAPLAN:
15
             Would you be sad if we said we're at the
                                                                               It's not a game. This is a real-life,
16
                                                              16
                                                                        O.
                                                                     serious situation in which plaintiffs are asking for
      conclusion of your deposition or would you be glad?
                                                              17
17
                                                                     millions of dollars, millions and millions of dollars,
              Well, I would be glad.
                                                              18
18
                                                              19
                                                                     from our clients.
              I do hope that if the Miller firm and
19
                                                                             They're accusing our clients of
      Motley Rice feel that there is more evidence and they
                                                              20
20
                                                                     wrongdoing. We're doing our best to defend our
                                                              21
      want to fight this FDA observation, that they will
21
      feel free to do it even if it's not wise to have me on
                                                              22
                                                                     clients.
22
                                                                              You understand that?
      the witness stand under questioning.
                                                              23
23
                                                                              I understand the implications. And I've
              I would hope that the fact that I have
                                                              24
                                                                        A.
24
                                                                     used words about myself that may or may not be
      come to the point where I'd say this FDA press release
                                                              25
25
                                                                                                             Page 305
                                               Page 303
                                                                     appropriate descriptors.
                                                                1
      and the fact that they probably have the documentation
 1
                                                                             This is a very big case, and I expressed
                                                                2
      that I didn't have might negate any further analysis
 2
                                                                     concern from the outset that my role, particularly as
                                                                3
      by me negligible.
 3
                                                                     things started to be disclosed that this was more than
                                                                4
 4
              If there are people who can get that
                                                                     I had originally agreed to do, would not jeopardize
 5
      evidence and continue this, where it may not be wise
                                                                5
      for me to do it, under no circumstances do I want my
                                                                6
                                                                     the correct outcome of the case.
 6
                                                                7
                                                                             There is a chance that there's -- my
 7
      present testimony to inhibit their further pursuit of
                                                                     insecurity with my inexperience at this that's causing
                                                                8
      truth if there is evidence that the FDA opinion should
 8
                                                                     the problem. And I don't want to hurt anybody.
                                                                9
 9
      be contradicted.
                                                              10
                                                                             I want this to actually -- people said
10
              Right now, I have not been presented
                                                                     just seek to come to truth. And that's what they're
      any. But I do want to go on record that these people
11
                                                              11
                                                                     asking you to do.
      hired me, and I'm in a very difficult situation right
                                                              12
12
                                                                        Q. And that's what you've done today to the
                                                              13
13
      now.
              And under no circumstances do I want to
                                                              14
                                                                     best of your ability, to seek the truth, to seek to
14
                                                              15
                                                                     testify to the truth; correct?
      undermine their position if they want to continue this
15
                                                                              I believe that. I do have some fears
                                                              16
      course of litigation.
16
                                                                     that there could be people who would want to fight the
                                                              17
              I think it -- I'm pretty comfortable
17
                                                                     FDA. I know there's people who do this.
      with where I've had to come based on what I've
                                                               18
18
                                                                             And there's a chance that that's what
                                                               19
19
      presented, and I guess --
                                                                     this case will evolve into. But at this point, you've
              MR. THOMPSON: Okay.
                                                              20
20
                                                                     presented me with a witness that I believe overrules
              THE WITNESS: -- I have to stop talking.
                                                              21
21
                                                              22
              MR. DEAN: Let's go off the record.
22
                                                               23
                                                                             MR. DEAN: Thank you.
               We're finished.
23
                                                                             MR. KAPLAN: All right. Thank you.
                                                               24
24
      BY MR. KAPLAN:
                                                                             MR. DEAN: Let's go off the record.
                                                               25
               You don't have to. I mean, I want you
25
```

77 (Pages 302 to 305)

Videotaped

June 30, 2010

1/U1 (en A. Frank, M.D. Video	
	Page 306	
1	VIDEO OPERATOR: Any more questions?	
2	MR. DEAN: No more questions.	
3	VIDEO OPERATOR: We are now going off	•
4	the video record.	
5	This is the end of Tape 6 and concludes	
6	the videotaped deposition of Karen A. Frank, M.D., on	
7	June 30th, 2010.	
8	The time is 5:39 p.m.	
9	(Witness excused.)	
10	(The deposition concluded at 5:39 p.m.)	
11		
12		
13		
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16		
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18		
19		
20		
21		
22		
23		
24		
25		
	Page 307	
1	WITNESS CERTIFICATION	
2	William Chiline	
3		
4		
5	I hereby certify that I have read	
6	the foregoing transcript of my deposition testimony,	
7	and that my answers to the questions propounded, with	
8	the attached corrections or changes, if any, are true	
9	and correct.	
10		
11		
12		
13		
14		
15	DATE KAREN A. FRANK, M.D.	
16		
17		
18		
19	PRINTED NAME	
20		
21		
22		
23		
24		
25		

78 (Pages 306 to 307)

Videotaped

June 30, 2010

Taccess ZZ:10 15Z:7U				
access 22:16 132:20	142:21 143:23	235:24 256:9	adverse 18:25 76:3	25:2 42:15 75:2
accepts 148:19	108:20 139:5	229:5 230:3	100:11	ago 16:23 17:23
accepted 181:16	106:14 107:8	225:13 227:6	adulteration	agnostic 123:2
298:4	73:9 90:13 102:2	139:1 166:2 207:9	adulterated 100:17	aggressive 101:5,13
accept 101.10	19:4 26:11 67:3	79:6 81:17 107:18	ADR 74:12	185:17
accept 181:16	Actavis 4:22,23	46:19 71:10 79:6	admonition 62:19	143:5 148:20
78:14	295:3	24:2,5,6,8 42:6	admittedly 118:19	125:14 126:1
abstractions 75:13	act 127:13 252:10	22:12 23:16,18	248:13	101:25 103:6
74:9,11 149:12	acronym 112:6	additional 15:25	admitted 120:20	73:4 74:14 79:20
abstracted 71:20	acquisitions 155:3	addition 182:7	289:21	aggregate 72:23
abstract 117:24	214:6,20,21	adamant 59:8	admit 205:12	agents 97:4
228:10 261:8	155:7,10 190:1	241:4	admissions 274:21	170:20
164:22 192:22	149:16 154:17	171:24 174:19	55:2	100:6 154:23
absolutely 104:13	acquisition 143:9	123:15 136:5	admins 54:3,19	agency 99:11,14,17
absolute 180:23	acquiring 189:24	112:6 119:5 123:3	106:9	287:11
216:13	175:22	actual 76:16 93:14	Administrative	afternoon 70:6
absent 46:17	acquired 151:11	activists 151:8	ADE 's 51:4	304:11
absences 71:24	165:16	270:3	292:22 293:21	126:10 227:2
267:3 271:8	acknowledge	actively 131:21	161:17 190:4	afraid 13:8 126:6
235:21 253:12	293:20 304:20	280:22,25 281:10	adequately 82:7	214:4
214:22 217:25	accusing 289:6	243:14 259:17	293:17	affiliates 210:5
123:13 210:1,2,12	258:17 260:18,20	173:4,6,10 193:10	281:24 289:11	affiliate 211:6
119:21 121:1	accused 199:12	170:19 172:8,13	248:24 279:25	187:6 286:9
85:13,14 93:25	227:19	166:25 167:2,5	192:7 237:1,4,6	102:11 134:11
64:4 71:5 80:20	29:1 123:19	109:10 165:19	178:24 180:4	AERs 73:14 88:20
absence 51:3 62:9	accurately 26:8	108:16,21,23	76:5 109:11	AER 72:19 113:15
abnormality 298:7	84:5 166:5 192:4	107:23 108:2,15	adequate 59:10	advocate 80:9 83:2
abnormal 272:1	81:5 82:10,12	actions 101:13	290:16 293:2	22:4 95:21
297:16 304:1	18:6 80:17,24	255:7	287:16 289:18	advisory 16:12
267:7 295:18	accurate 11:5,7	172:17 173:24	281:5,7,9,13	advisable 293:1
259:15 263:5	244:13	164:19 167:9	173:9 280:24	180:2 220:25
244:23 248:6	159:23 230:4	150:25 159:4	170:7 171:16	advice 56:14 57:2
214:9 236:25	accuracy 131:24	100:6 101:5	160:11 167:5	299:22 302:9
153:25 174:10	193:22 194:24	action 99:11,14,17	108:16 159:4	274:13 280:21
77:15 150:18	144:12 178:22	acting 30:3	86:1 92:15 93:23	270:8 273:1 274:8
able 23:18 51:13	account 140:16	269:18 287:5	70:13 76:6 85:22	210:14 266:1
305:14	284:2	216:6,25 247:12	adequacy 48:22	i i
239:4 245:6	234:14 235:4	213:24 214:1,17	ADE 280:25 281:13	168:23 187:7
224:17 233:15	accompanying	· ·		164:18 166:13
ability 220:12	118:10	187:17 188:1,23 193:10 208:8	addressing 136:9 162:18	139:5,13 140:4
abilities 238:21	accidentally 69:14	185:22,23 187:12		139:5,13 140:4
117:6,10,18 119:6	289:23		96:8	135:20 137:7
abandoned 116:16	270:24 271:13	166:14 168:23 169:20 171:17	addressed 25:12	132:13 134:8
abandon 304:8			136:9 195:16	89:7,17 110:4
A		·		
	134:12,13 196:21 234:17 235:1	144:7,13 150:5 163:2 164:7	address 9:12 23:1 80:5 83:15 86:25	76:4 78:6,8,15 86:15 88:15 89:4

Videotaped

June 30, 2010

				rage 307
80:2 144:22	285:12 292:19,20	161:14 169:9	155:25 174:2	APPEARANCES
146:13 219:24	296:10	174:16 179:22	176:3 182:12	2:1
225:18 230:6,14	aided 230:18	198:21 209:4	188:24 195:9,10	appeared 234:7
299:19	aiming 222:5	215:15 229:8	203:15 207:23	appears 281:6
agree 53:6,9 72:18	aired 125:4	248:15 250:20,22	213:19 221:24	291:3
86:24 100:5 101:3	Airport 44:1	259:18 270:25	229:19 230:15	appendices 148:23
102:10,14 107:3	alarm 153:13	282:5,14 283:11	231:12 236:13	appendix 74:24
110:2 118:17	197:20	286:16 298:20	239:16 240:15	277:17,17
110.2 116.17	alert 87:10 105:16	303:2	250:3 252:6	apply 299:21
135:19 137:5	106:20 107:5,9	analysts 27:15	254:12 259:15	appreciate 35:17
140:19 144:16	108:7 109:3 172:5	analytical 146:22	271:18 272:23	69:13 290:4,5
148:25 157:6	alerts 172:3	181:18 248:8,15	282:22 285:5	approached 16:22
162:16 163:1	algorithm 111:11	analytically 123:18	286:19 297:18	55:10,21,24 57:12
162.16 163.1	114:13	181:15	answered 20:24	59:6 95:12 109:19
170:12 176:11,17	allegation 127:25	analytics 61:6	24:15 66:25	222:7,10
183:10,21 184:9	262:24	88:10 119:8	262:13 270:14	appropriate 16:8
185:10,21 164.9	allegations 261:16	analyze 25:24	answering 52:4	25:20 59:12 76:13
188:3 196:25	allege 121:24	112:17 205:6	answers 27:24 66:3	142:15 169:19
197:24 198:2	alleged 150:15	224:18	166:19 297:16	170:14,19 193:16
203:5 207:17	alleging 127:18	analyzed 147:23	307:7	220:2 230:8 234:9
203.3 207.17	allow 18:1 27:21	analyzes 112:3	anti 94:22	239:13 292:13
241:1,24 280:13	51:3 70:18 74:22	analyzing 172:25	anticipated 12:19	305:1
295:24 297:24	82:11 102:3 103:7	283:4	179:20 181:13	appropriately
293:24 297.24	119:8 193:9	Anderton 145:23	anticipating 27:8	56:17 67:12 179:3
agreeable 73:19	255:14	Angeles 2:13	antimicrobial	195:4 232:20
agreed 138:22	allowed 138:17	Ann 5:14	95:22	234:8 260:15
168:21 237:24	277:1 278:1	annotate 149:20	anti-infective 95:2	approval 201:25
239:18,19,25	allows 113:8	annotated 149:23	anti-infectives	224:9
240:24 252:9	117:21 191:22	annotation 149:21	94:25	approved 173:14
260:2 298:16	alter 30:18	153:9 157:3	anxiety 181:17	175:6 197:25
305:5	alterations 9:4	announced 147:5	anxious 123:5	198:10,11,16
	amazed 227:15	262:18	anybody 160:9	199:1 223:18
agreement 3:14	Amide 66:21 73:9	answer 6:20 14:9	284:23 285:25	approximate 43:20
57:16 58:11,14 154:18 155:14	150:5 151:4,7,8	14:14 17:7,10	292:14 293:20	approximately
i	150:3 131:4,7,8	18:5,7 24:20	305:9	15:8 42:1
157:22 158:4 175:4 187:4 212:3	· ·	35:17 47:12 73:18	anyway 28:8 209:7	April 185:24
	amount 34:4 81:17	74:3 77:5 82:24	apologize 28:16	188:12 201:15,20
214:7	82:18 187:20	83:13 89:12 91:1	40:11 153:9	202:4 203:13
agreements 25:10	293:9	91:2,25 92:1	apparently 85:16	204:18,20 205:23
191:20 ahead 14:4 44:21	amounts 248:7	93:11 98:20 99:15	169:5 173:23	205:25 206:6,8,13
	analysis 3:21 16:3	122:19,20 125:5	178:16 185:15	206:23 207:6
45:7 63:21 69:23	18:2 19:2,4 26:4	125:23 130:6	186:5	208:8 216:23
74:3 80:14 83:10	61:10 73:25 74:14	135:18 138:1	appear 9:25 75:19	272:8 273:4,6
83:13 96:24	79:20 87:17	142:16 143:25	164:20 243:21	arbitrary 41:12
133:19 139:11	111:10 137:10	144:2,9,9 151:15	280:23	157:21
178:10 285:9,9,10	111.10 137.10	177.2,7,7 131.13	200.23	
		I .	1	•

				Page 31
06.16.105.15	005 14 007 00 04	104.14 105.22 24	assumption 64:5	212:2 278:18,25
area 96:16 105:17	225:14 227:22,24	194:14 195:23,24	75:8,12 76:2,9,19	authoritative
116:9,10 120:4	235:17 238:6,18	196:11 200:14	75:8,12 76.2,9,19	270:14
142:6 190:11	240:13 242:10	202:23 203:20,22	116:7 122:12	authorities 49:3
207:11 213:4,9,22	243:9,13 246:6,13	204:7 208:4,15,17		56:6 73:4 190:3
223:21	248:19,19 249:14	208:24 209:3,17	126:15 133:12	
areas 96:14	249:20,23 252:5	215:11 234:15	137:9 154:13	210:13 212:8
argue 238:25 239:1	252:15 253:13,15	235:15,16 236:21	208:14 209:16	authority 72:24
arguing 304:9	256:10 259:16	241:15,21 242:17	210:20 292:4	210:16,22
argument 299:24	261:22 262:12,16	250:13 263:19	assumptions 134:3	available 7:16 26:2
300:6	269:3,11 271:12	264:13 275:5	208:19 291:4	31:5,10 52:12
arisen 231:4 244:17	271:17 272:24	286:18	assurance 97:18	68:18 112:5
arising 86:16	276:9 282:21,25	assessments 51:23	120:21 214:23	122:14 124:18
array 86:14	290:6 293:7,9	60:22 63:7 64:4	222:20 227:13	133:3,5 146:8,9
arrive 68:10	297:18	75:7 77:13 88:7	244:13 245:13,21	230:17 272:19
arrived 15:14	asking 6:9 29:19	88:12 92:13,16,24	245:21 304:6	288:3
207:3,4 294:24	52:21 56:7 63:13	98:9 110:16	assurances 217:22	Avenue 2:9
300:18	64:4 125:7 239:8	114:17 215:12	assure 246:20	average 227:13
articulate 245:21	260:25 261:24	234:19 235:5	assured 245:12,15	avoid 31:19 300:3
articulated 299:17	266:7 268:17	288:11	attached 183:9,10	avoided 220:7
artifact 200:2	300:10 301:12	assigned 96:3	307:8	222:4
ascertain 300:19	304:17 305:12	assignment 56:24	attachment 277:9	aware 15:25 42:20
aside 115:2 192:17	assess 74:20 91:23	57:7,12 58:20	278:10	97:23 98:2 103:11
192:25	92:14 119:13	59:12 80:4 208:19	attempt 110:8	115:9,10,12 117:4
asked 9:12 10:6,9	123:8 160:5,13	222:11 224:7	111:15 114:5	117:5 127:14,16
30:6,9 31:9 32:20	161:15 219:11	227:17 241:10	163:21 180:3	127:24 130:2
38:15 48:17 49:18	233:15 234:13	244:12 260:2,7,13	224:13 231:1	154:8 158:2
56:16 62:22 65:2	236:20 246:12	292:22	249:15 289:4	164:13 187:16
66:16 70:12,16,21	260:9 269:21	assist 70:5	attempted 249:22	191:3,12,16,18,19
71:3 73:12,13	280:25	assisted 96:25	269:18	192:10 193:1
80:2,5 81:7 83:20	assessing 110:18	108:14	attempting 190:2	195:2 216:17,22
99:23 100:12	123:11 159:4	assisting 27:15	attention 105:25	216:24 241:15
117:14 122:23	172:3	associated 76:11	106:19 129:9	274:22 300:11,17
127:2 136:9	assessment 3:20	119:24	130:8,15 131:10	awareness 273:8
138:25 142:6	10:7,8 26:23	association 91:8	148:9 269:3,11	awful 219:8
146:13 160:5	70:23 71:6 73:6,7	assume 37:9 133:2	attorney 15:4 30:3	a.m 1:14 4:14 64:16
170:9 177:6	74:6,13,18,23	133:8 135:12	59:13	64:17,18,22
178:19,23 179:2	80:24 82:11,12	157:13 235:12	attorneys 14:19	104:20,24
179:21,23 181:9	84:5 89:1,21 91:8	236:15	38:10,16 56:25	
192:9 195:19	103:8 111:7,7,9	assumed 63:24	59:23 65:12 81:9	B
196:14 199:23	114:19,19 118:16	76:17 181:12	213:21 217:4	B 187:9 203:3,11
201:11 203:2	119:9,11 120:17	244:20	220:15 295:13	203:14
205:4,6,7 208:20	123:3 136:5	assuming 17:14	attorney's 195:22	back 8:9 12:8,15
213:5 218:1	137:13 157:20	134:10 141:9	August 150:20,20	13:9 14:10 17:8
219:16 222:11	169:13,22 171:5	167:10 169:11	163:5 165:13	21:23 26:3 31:9
223:3,5,9 224:21	172:5 177:11	271:3 272:25	187:3 188:10	33:22 34:9,18
440.09097 44T.41	1,2.5 1,1.11			
		•	-	

Videotaped

June 30, 2010

				Page 311
20.10.10.0.10.0	D 21651	025 10 226.2	269.10 270.11	162,20
39:19 43:8 49:2	Bacon 2:16 5:1	235:19 236:3	268:10 270:11 272:7 277:24	163:20 blank 244:20
51:19 52:2 54:22	bacteriology 61:8	246:16 252:23		blanket 192:3
58:5 59:3 61:5,8	bad 284:17,19	253:4	282:10 287:1,22 291:16,16 292:7	blanking 112:5
62:18 64:19 75:23	base 85:3 94:2	batch 87:11,14	·	blanks 7:10
76:21 82:22 93:10	177:18 193:16	103:9 117:5 118:4	305:16,21	blend 117:17,23
93:10 98:3 99:12	225:19 229:16	119:15 120:8,9,11	Bellingham 62:16 102:25	119:24 120:2
103:4 104:22	234:24 288:3	120:15,18 158:6 158:23 266:9	bells 153:13	blue 163:19
106:6 111:14	based 26:15 47:3	batches 61:12 89:1	benefit 20:14	book 43:18
121:13 127:16	53:4 59:9 80:17		best 27:23 50:15	bother 237:12
130:21 137:4	83:23 92:7 95:17	89:3,9,23 103:21 118:5 270:25	59:1 112:23	bothered 117:8
143:7,9 144:2,3	111:10 114:10		132:10 138:22	bothering 69:8
146:12 147:5	119:18 122:13	Bates 67:4 204:15	139:2 156:1 179:8	bottle 118:6,8,9
149:18,22 152:7	155:25 157:21	bears 67:3	217:14,17 228:22	266:11
168:15 175:3,8,10	161:18 171:2	beg 209:20 began 56:14	236:17 246:21	bottles 118:7
175:18 178:19	174:25 176:2,4,10		249:15 258:8,18	119:16
180:21 181:17,21	179:8 180:12,24	beginning 21:10,20 42:3 241:11	265:24 270:6	bottom 106:8
182:12 188:14,24 189:11,22 190:9	209:3 217:12,14 217:20 218:2,6	begins 279:16,21	282:20 304:21	161:18 186:11,14
· · · · · · · · · · · · · · · · · · ·	220:8,23 221:9,17	begun 146:3	305:14	209:23,25 252:9
197:2 198:21	220.8,23 221.9,17	behalf 6:4 30:3	beyond 23:13 91:10	267:12 271:16
199:11 208:21,25	242:18 245:4	80:10 83:2 123:22	283:13	Boulevard 2:4,16
209:23 210:17,22 212:8 215:25	246:21 247:24	237:16 247:12	BfArM 113:10	bounds 16:10
220:18 221:7	253:10,11 255:5	295:3	bias 236:19	box 76:13 95:21
226:9 230:15	271:21 274:1	behavior 225:5	bibliography	96:1
232:12 247:8	278:4,18,25	believe 11:9,15	183:15,18	boy 163:15 300:22
252:12 247:8	279:24 282:16	15:15 16:9 22:2	big 128:18 136:19	brand 149:1 194:8
261:1 269:15	286:9 287:9,25	24:20 30:16 44:13	227:16 241:23	branded 140:8
271:5 277:12	288:16,22 289:13	50:5 51:21 54:3	260:7 275:6 277:9	break 6:25 7:1 64:7
280:16,17 281:18	289:17,24 293:8	54:11 58:19 62:13	277:17,17 305:2	168:2,4,6 215:19
284:9 285:20	293:18 294:8	63:5 67:11 91:14	bill 54:12 79:9,10	221:25
286:2 296:25	301:14 303:18	110:14 127:3	billed 79:14,19	Bridgeside 2:4
297:1	304:10	128:23 138:19	binder 39:5 42:13	brief 94:15
backed 227:9,18	baseline 172:21	139:9 144:11	43:3 59:21 67:12	briefly 49:9,11
292:5	basic 127:24	147:10 151:1	68:13,14,17,17	bring 29:19 30:5,12
background 3:21	169:17 202:3,9	152:6 155:9,20	69:3	38:15 61:5 132:23
25:11 59:10,20	basically 96:7	156:3 166:1,21	binders 12:16,18	242:17
142:14 148:7	113:24 167:8	172:2 183:10	32:13 36:7 39:1	bringing 25:18
184:22 185:1,14	258:11	185:24 204:24	42:17,19,19,22,24	broad 96:14,15
200:22 221:20	basing 48:12	220:24 226:22	54:13 68:2	267:3
250:20 254:18	basis 10:14 18:6	227:4 230:16	bioequivalence	broader 53:4
256:23 283:11	49:19 59:5 66:2	238:20,23 241:14	129:18,23,25	160:13 161:15
backing 229:4	132:6,7,17 165:21	242:13 249:10	bit 6:5,23 43:3	206:2
255:5	167:23 171:9	251:21,24 252:3	64:10 81:6 138:13	broke 168:21
backup 154:2	178:20 201:10	255:11 256:8,15	228:20 263:23	brought 22:22 33:1
219:18	210:6 218:15	257:24 267:17	black 95:21 96:1	33:9 37:25 65:20
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Videotaped

June 30, 2010

				- rage 312
((10.00.65.05	CABA 06:05 07:0	115.01 117.16	287:5,8 297:21,22	chain 173:21
66:18,20 67:2,7	CAPA 26:25 27:2	115:21 117:16 124:4 126:16	300:4,6,10,12	chair 285:7
67:22 83:25 94:22	248:11 CAPAs 26:25 27:3	124:4 126:16	casual 300:2	chairing 14:25
122:22 133:1,25	-	143:17 156:23	catalog 69:5 81:23	challenge 95:25
138:15 194:14	27:4 48:11,21	167:15 176:8	categorize 32:10	295:10,21
196:3 200:12	capture 50:24	186:3 188:17,19	causality 110:23	chance 6:4 23:13
build 82:6	cardiologist 23:5	5	113:1 114:6,10,11	128:22 277:22
building 2:9 27:16	cardiologists	194:6,20,21,23,25 198:20 213:4	113.1 114.0,10,11	282:9 305:7,19
bulk 187:2 188:11	100:15		299:1	chances 266:10
bullet 145:4 269:5	cardiologist's	216:16 217:4	causation 111:16	change 158:14,15
269:12,16,16,25	136:3	220:13 225:8	cause 61:10 161:14	195:20 196:1,10
272:25	cardiovascular	227:16 236:16	caused 110:4 280:9	196:15 197:19
bunch 241:16	95:1	238:8 239:15		190:13 197:19
243:25 287:5	cardio-renal 94:20	241:17,20 242:17	280:14	201:12 219:16
business 27:13,14	94:24	243:15,21 244:15	causing 305:8	201:12 219:16 225:25 231:7
27:16 58:16 60:18	care 71:7 236:17	248:10 249:11	caution 70:3 134:4	242:19 285:13
63:14 65:19 66:5	careful 16:9 119:12	255:9 260:7	cautious 122:23	changed 64:8
82:15 162:24	119:20 141:23	261:12,21 262:2	132:2 133:15 181:20	196:15 266:19
195:25 261:3	142:2 144:12	268:7 271:4 275:8		changes 70:21 71:4
business-to-busi	147:13 157:3	276:18 280:3	CDs 30:25 31:3,7	196:10,12,17
70:24 71:6	172:22 174:16	289:11 292:24	31:14 Celsius 116:4	200:16,24 201:11
<u>C</u>	181:15,18 219:6	296:1 299:2	centralization	202:1 203:3 205:3
	228:3,5 229:8	300:11 301:16		202.1 203.3 203.3
C 112:11 203:3,11	250:10 291:7	302:11 305:2,6,20	212:20,23 centralized 210:3	219:19 307:8
203:14 calculated 190:7	carefully 12:20	cases 18:22,22,25	centrainzeu 210.3 certain 25:8 29:19	characterize
	16:14,17 33:22	25:19 55:10 75:24	56:3 60:23 68:14	265:15
California 2:13	35:11 50:14 51:3	75:25 77:14 85:11	104:13 130:13	charge 138:1
call 13:3 14:24,25	51:10 53:11 132:5	87:8,10 88:5,13		253:19,20,21,22
15:7,14 41:13	140:17 172:25	100:22 127:20	141:24 199:23	Charleston 1:2
46:7 130:8 158:10	182:19 196:17	130:2 139:19,24	205:5 225:3	4:10 255:21
195:17 242:14	222:11 228:1	140:1 143:1,2,12	237:21 239:7	Charlie 112:11
called 15:13 32:10	256:14	143:18 153:24	248:20 249:5,7,21	chart 78:3
35:18 44:18 46:17		156:11,16 157:12	255:9 290:11	check 20:17 43:18
54:3 115:10 116:2	carries 301:20	157:14 158:7	296:20	54:12 61:7 204:6
116:4 133:6 151:3	Carter 7:13 14:21	161:21 178:7,16	certainly 19:7,8	checks 31:15
250:22 253:23	44:1 50:6 56:12	182:9,13 185:16	68:19 254:25	choose 257:5
265:19	65:21 177:7	186:2,2,4 188:11	257:20 262:8	_
calling 52:7	case 3:15 23:11	188:15,25 189:12	certainty 297:8	chronological 236:7
calls 36:20 274:15	30:8 59:7 62:3	189:14,17 191:18	CERTIFICATI	CIOMS 72:22 73:2
camera 41:17	70:11,15 71:15	191:22 193:17	307:1	78:8 88:23 103:5
cancer 301:3	72:10 74:13 76:8	194:14 210:14	Certified 1:15,16	110:11,11,12,14
cancers 301:4	80:7 81:12 85:10	211:1,21 212:7	certify 307:5	110:11,11,12,14
candor 290:4	85:13 86:19,19,20	216:10,11 218:14	CFR 98:22	110:17,18,19
292:11 297:10	87:16,21 88:4	231:4 243:19	CGMP 106:2	111:12,18 113:3,9
cap 79:1,3,3,4,4,9	99:19 101:24	255:24 262:17	269:24 275:23	113:14,21,22
79:15	102:8 103:15	273:16,19,20,21	276:4	114.7,7
		1		

Videotaped

June 30, 2010

				Page 313
circle 264:18	client 36:19 58:22	collection 156:11	commentary 125:2	community 71:8
266:22	218:6 228:24,25	color 3:19 70:3	commented 62:8	125:18
circumscribed	259:20 304:8	column 78:6	153:12 196:13	companies 25:13
	clients 60:25	combine 10:9	commenting	27:3 28:19 29:6
circumstances	260:18,20,22	combined 10:5	135:22 145:15	61:1,20 65:18
161:23 180:5	261:6,17 304:19	12:1	300:3	86:14 88:18,19
192:10 193:1,14	304:20,22	come 15:20 17:13	comments 10:14	89:19 90:3 95:24
	clinical 97:24,24	21:12,23 29:2	12:14 30:17 33:21	110:18 111:3
cite 60:6 75:25	130:4 133:23	40:20,21 43:7,8	33:23 34:9,10,17	113:20 148:21
298:25 301:22	134:1 162:22	52:4 126:8 130:21	35:8,9,10 49:4	151:11 211:4,5
302:2	196:4 200:7	134:5 149:11	71:12,17,19 83:4	213:2 214:21
cited 189:18 216:11	202:13 274:1	210:24 212:8	110:11,13 113:21	254:5 275:1
Citrix 22:18	275:4 299:8	229:2 235:2	114:9 180:20	company 12:22
City 2:17	clinician's 274:9	240:14 263:19	219:7 224:7	25:25 26:21 28:20
civil 50:18	close 34:5 49:14	264:18 266:22	250:11 267:1	48:11,18,20 49:3
clarification 282:3	52:4	268:8 270:20	committee 112:2	51:6 53:1 57:11
clarified 157:11	closed-door 16:13	271:18 289:13	committees 16:12	60:18 61:17 66:11
194:13	closely 51:12 80:25	302:25 303:18	common 274:13	74:25 80:22 82:13
clarify 77:3,6	closeout 162:10	305:11	commonplace	82:18 85:14 87:16
115:11 130:22	175:9,9 184:10,19	comes 212:6	161:9	87:23 88:12 89:14
157:18 175:7	185:12,20,21	comfort 241:6	communicate 6:11	98:23 99:1 101:4
clarifying 99:4	188:22 199:4,5	comfortable 21:21	communicated	101:6,12,14
class 95:8,22 96:1	closet 42:17	180:8 221:10	91:20 155:16	102:25 103:25
classes 120:6	cluster 87:17	253:14 257:8	237:25	105:10,13 110:1
Classically 87:5	clustering 87:8,10	288:20 303:17	communication	110:17,22,24
classified 150:23	coached 25:17	coming 178:18	3:21 10:8 36:1	111:4,7,9 113:8
clean 173:23	36:17 65:10	290:25	70:22 71:7,10	113:22 114:23
248:23	coaching 13:5 16:8	commencing 1:14	90:4,14 92:3	115:13 116:1,3
cleaned 42:16	16:10 23:2 56:13	comment 25:18	156:21 163:9	131:21 143:6
clear 8:12 10:23	code 188:17 194:21	49:1 59:11 70:12	196:8,12 197:1	145:25 149:8,13
47:1,23 61:19	coded 75:9,11	70:21 72:4 76:12	198:12,13,13	151:3,4,5 158:14
63:1 69:5 93:12	142:23 143:12,16	81:21 92:23 102:9	199:16,18 200:25	160:2 161:6,13,21
100:16 134:6	287:7	111:12 122:17	201:13 202:6,24	163:3 165:17,23
137:6 165:8,18	codes 19:1 75:19,19	142:9 143:6,19	203:17 204:14	173:22 175:17
169:18 174:21,24	188:20	145:14 178:15	206:3 208:16	178:6 186:8
174:25 175:13	coding 74:12,12	189:9 190:9,17	209:18 234:1	189:24 197:2
197:1 296:19	75:3,4,6,15,17	196:14 199:23	240:10 241:19	205:23 209:5
clearer 66:17	76:10,16,18,23	201:12,23 203:2	communications	210:16,17,20
clearly 26:7 27:23	77:8,12,14,16	205:4 212:13	35:21 71:4 163:20	211:6,7 212:9
66:1 108:24 109:3	78:3,9,11,15,15	214:9 223:6,7	195:18 197:25	270:4 274:25
129:16 169:8	101:22,23 102:1,4	233:19 236:5	201:14 202:10	275:5,6 278:19
194:6 196:15,15	102:8 136:23	263:17,18,20	206:1 214:25	279:1,3
212:19 271:10	143:13 188:16	273:15 279:11	215:16 231:3	company's 49:1
Cleveland 2:10	coffee 287:11	281:18 287:16	246:4 247:1	114:19 163:19
CICTUININ A.IV				•
		1	287:10	compare 222:2
4:17	coincided 154:21	293:13 302:10	287:10	compare 222:2

Videotaped

June 30, 2010

			· · · · · · · · · · · · · · · · · · ·	
compared 9:1	144:13 156:17	255:4,13 271:17	246:6 268:7	237:19,23 238:7
compelled 135:18	160:10 172:14	288:10 297:2	280:24 281:4,7	248:3 251:23
competent 263:11	175:5 210:4 211:9	concerning 273:19	confirmation	255:2 286:7
263:25	211:24 212:22,25	concerns 22:25	157:16 173:9,12	consistency 269:22
competitive 95:13	228:14 230:8	23:1,10 25:3,6	231:21 239:8	consistent 173:13
compilation 53:5	231:17 233:20	46:16,24 47:4	281:8	consolidate 127:20
54:1,9	279:25 281:23	65:24 81:15 84:9	confirmatory 176:5	consolidated
compiling 108:12	284:3,4 289:18	84:20 85:1,21	247:1	253:19 255:22
complaint 61:15,21	compliant 169:5	92:9 101:4,18	confirmed 294:1	constitute 238:15
61:22 62:4,16	complicated 299:12	102:7 155:16	299:8 301:13	constituted 179:5
63:9 88:5,9 89:22	complies 49:10	165:5 219:2	confirming 109:6	constitutes 99:17
90:6 91:21 92:3	54:23	237:25 279:6	267:10	178:24
93:17,21 162:22	component 236:9	conclude 299:23	confronted 146:6	constructed 77:13
232:19 234:1,7,12	components 236:10	concluded 107:22	confronting 175:15	113:7
234:14	compound 140:8	306:10	confused 45:8	consultant 55:10
complaints 51:4	comprehension	concludes 306:5	confusing 173:21	55:11 63:25
58:18 60:19 62:11	196:5	conclusion 8:16	confusion 234:21	consultants 246:12
62:22,25 63:3,7	comprise 31:8	10:10 34:17 71:16	Congress 133:7	consulting 3:14
63:10 64:1 89:12	compulsive 119:2,2	71:20,22 72:5	141:12	27:12,14 33:16
89:16 90:17 91:4	computer 132:21	137:13 155:19	Congressional	55:9,24 56:25
91:12 103:2 104:5	conceive 70:10	159:21 167:22	123:25 132:3	57:4,11,16,23
104:10 107:18	concentrating	169:2,16,17 224:9	297:5	58:15,20 78:25
231:17,18 232:1	123:18	230:8,21 270:21	conjunction 211:7	79:8 109:18 218:6
232:23,24 233:13	concern 22:23	290:24 291:1,10	connect 207:14	240:10,22 245:18
233:16,21 234:11	25:21 28:17 80:15	302:17	connection 11:14	consumer 262:25
complete 26:1	92:23 93:25 156:5	conclusions 3:21	conscience 217:5	298:23 299:17
52:14 53:4 80:18	160:17 177:17,19	34:11 72:2,6	220:1	301:16
84:6 85:2 277:19	179:15 198:23	74:20 108:6 109:7	conscionable	consumers 122:6
completely 25:24	235:3,20 237:18	167:15 169:21	218:18 219:23	139:7 272:19
59:10 71:20 80:21	250:12 259:4,8	180:23 231:23	220:4	contain 71:14 74:8
84:2 127:5 142:5	260:16,17,17	250:20,23,25	consent 26:12 60:7	74:21 76:16,16
142:9 143:10	266:6 286:12	282:6 283:11	82:4 142:20	89:21 110:11
172:12,23 178:9	288:13 292:21	concomitant	149:15 151:19,20	113:24 114:9
181:12 220:6	296:12,22 304:5	216:14 298:7	173:22 200:7	139:19
227:20 234:22	305:3	concordance 114:8	245:2	contained 34:23
244:5 254:22	concerned 26:1	concurrent 216:14	consents 196:4	39:25 59:24 76:24
282:10 289:11,16	27:24 34:2 42:12	condition 298:3	consequences	77:9 104:3 137:18
289:23	44:18 48:16 83:21	confer 257:17,25	258:22 259:2	163:4 204:25
completeness 83:22	84:4 87:9 89:14	confidence 244:4	conservative	207:20 208:6
complex 12:22	173:12 177:15,20	251:16 254:6	126:14	247:19 250:19
173:21 225:8	179:12 185:2	256:5 263:13	consider 63:13	254:2 282:5,22
complexity 28:18	192:15 198:4	286:23	109:10 214:24	contains 39:12 42:6
34:3 51:6	217:6 227:8,18	confidentiality	277:1	77:24 88:21,23
compliance 27:4,17	234:18 246:3	25:9 58:21	considered 49:23	114:4 208:3
66:12 81:19	251:13 254:17	confirm 63:14	107:23 114:21	content 70:18
	•			<u> </u>
	22.00			u

Videotaped

June 30, 2010

				Page 315
21 (12 200 1	0.12.15.20.0	164:21 165:4	correlates 173:12	254:21 256:5
216:12 280:1	copy 8:12,15 20:8	164:21 163:4	correspondence	259:21 285:20
281:6,24 284:16	20:16 30:19,19	168:23 170:10	30:2 35:20 36:1	295:10 296:16
Contents 3:3,5	31:8 45:1 57:16	176:6 178:1	38:1,5 143:5	courtroom 253:17
40:18 41:8,21	57:21,24 58:11		149:13 160:16	253:23
42:9 43:12 45:14	61:3 66:18 70:3,4	182:22 183:22		Court-imposed
46:22 54:2,9	199:13 207:10,10	185:22 188:3	correspondences 151:8	226:18
59:25	207:16 209:10	190:25 195:5 197:10 200:19		cover 36:6,8,12
context 86:2,5	233:5 280:6		corresponding 30:8	38:7 40:10,15,15
102:10 109:23	core 237:4	202:7 204:22	couch 289:3	40:16,24 152:2
138:16 143:10	corporate 155:2	205:1,14,25 206:8	couch 289:3 counsel 4:19 84:21	203:23 204:5,6
164:24 167:1	correct 5:15,23 8:8	206:21,23 207:4		205.25 204.5,0
169:3,10	8:12,24 9:8 14:17	207:12 208:8	85:20 122:21 124:8 145:7 146:4	200:10,20 200:23
continue 27:22	24:11,13 28:20,23	209:9 213:10	l '	covered 87:15
169:12 229:16	31:1,21 35:22,23	215:9 221:23	156:14 177:2	100:15 185:25
237:16 239:14	37:17 38:25 39:14	222:14 223:23	213:3 218:20	
258:1 303:5,15	39:23 40:2,18	225:20,25 229:1	219:3 220:25	covering 27:20
continues 266:16	41:21,24 42:9	229:18 234:8	221:1 224:16	creating 125:17
contradict 291:12	43:13 45:18 46:24	235:11 240:2,4,6	248:20 249:7,12	credibility 224:11 225:1 231:11
contradicted 303:9	47:17 49:22 58:12	242:2,5 244:10	249:18,24 251:8	259:3
contrary 166:9	61:23 63:4,17	250:20 251:3	260:25	
248:22	66:22 67:4,14,18	254:4 255:15	counted 282:18	critical 162:24
control 97:13	68:5 72:11,20	265:2,21 266:4,22	country 194:21	212:25
120:21 162:14,15	73:25 75:20 76:25	298:11 305:6,15	211:5	criticism 133:6
162:21	77:2,25 78:12	307:9	country-specific	199:15 216:22
convention 79:2	79:25 82:19,19	corrected 28:22	113:13 148:23	criticisms 216:4,24
conventional	84:15,24 85:4,23	82:7,8,8 146:21	couple 64:24	critique 238:18
210:25	86:3,8,11 87:4,24	147:15 163:10	120:12 127:22	CSC 109:16
conventions 102:1	89:9,20 90:8 93:1	173:25 174:1	130:24 147:6	current 269:23
109:20	93:3,7 94:6,6,8	190:5 259:18	158:23 191:15	curriculum 30:1
conversation 58:25	98:12 100:7,11,23	correction 28:23	222:8 272:3	curve 225:2
142:15 223:23	100:25 101:1,18	corrections 307:8	course 12:21,23	customer 70:24
conversations	106:5,11,14,16	corrective 107:23	13:11 42:11 82:11	71:6 204:12,20
287:11 300:1,2	107:6,9,15,20,25	108:2,15,16,21,22	119:13 230:5	205:17,19 207:18
convey 44:10 220:3	108:3,23 110:9	109:10 159:4	233:21,25 255:7	207:21 208:5
conveyed 202:6	111:16 113:25	160:18 161:7	259:9 303:16	customers 195:24
convoluted 51:2	114:2,15 116:12	164:19 165:18	court 1:1 4:1,9,16	195:25
coordinators	120:22 121:2	166:25 167:2,5,9	4:17 5:25 6:15	cycle 154:13
202:15	124:8,13,16,22	170:19 172:8,13	116:24 141:12	C-I-O-M-S 112:9
Copenhagen	127:18 128:1,5,23	172:17 173:4,6,9	144:3 166:7	D
155:17 156:16	131:7 133:9,12	173:24 259:17	177:13 181:5	
158:6,11,12	134:9,14 135:13	280:22,25 281:9	222:3,23 230:15	D3:2
211:21,25	137:8,13 140:14	correctly 9:16 43:1	239:11,17,22	daily 118:11 200:11
copies 7:18,18 12:4	146:14 147:1,11	129:10 132:15	241:11 242:1,10	200:16 204:21
12:4 33:9 45:2,12	154:23 157:8,10	213:12 219:5	243:5 244:10	207:19 208:2
56:16 64:9 198:4	160:18 164:8,14	228:10 289:6	251:14 253:25	dangerous 172:25
			<u> </u>	

Videotaped

June 30, 2010

	i	I	•	•
David 2:19 4:15	138:5 139:10	175:24 190:7	uenciencies 150.15	211.13
208:22 212:5,5 David 2:10 4:15	134:24 137:3,17	decisions 157:21	deficiencies 150:15	211:13
dates 149:14,16	128:21 133:18	215:14 296:18	defensible 289:1	departments
273:4 279:1	121:4,17 127:10	186:8 214:6	68:18	deny 169:14
208:23 250:18	117:7 118:12,23	158:9,17 169:4	275:14,22 280:4 defense 59:19	188:11
187:11,17 206:23	112:15 116:22	127:8 154:17	183:7 268:25	Denmark 186:24
dated 164:7 165:16	101:10 104:16,25	decision 46:19	145:19 163:24	245:19
307:15	93:5 94:11 96:13	80:23 95:24	Defendant's 8:8	Denise 55:16
276:14,16 278:24	80:13 83:9 84:18	decided 50:25	243:16,17	97:3
273:2 276:4,7,8	77:17,19,22 79:17	212:21	230:18,25 231:8	224:12,17 demonstrating
272:9,12,13,22,24	72:17 73:10 74:2	decentralized	69:20 118:16	224:12,17
212:2 242:12	69:17,23 70:1,8,9	decent 224:13	4:22,24 68:12	demonstrates
204:5 205:13,15	64:7,23 68:22,25	276:6	defendants 2:7	demonstrated 239:4
158:10,11 192:12	58:10 59:18 60:15	108:24 109:1,2	53:21 60:16	301:6,8,15
135:10 155:15	55:6 57:25 58:4	December 106:16	Defendant 4:7	demonstrate 301:1
134:19,23 135:3	48:1 53:15,19	decade 134:5	defend 304:21	
57:15,18 76:7,8	45:2,6,11 47:22	death 216:15	defects 88:25	delivered 31:12 68:3 145:22
date 43:18,18,19	41:19 43:6 44:19	207:17,21 208:5	260:23 262:9,25	deliver 180:3
113:6,7,12	35:14 41:5,11,15	204:20 205:17	defectively 128:4	delinquent 280:2
78:16 110:22	29:17 33:12,13	71:11,11 204:11	301:24	188:22
databases 19:3	28:5,9 29:13,16	Dear 70:24 71:1,2,6	298:22 300:19	184:3,14 187:23
287:5	20:9,13 22:5,7,9	Dean's 260:17	288:7 289:20	182:1,9,11 183:9
271:3,5 286:9	16:25 17:6 19:14	305:23,25 306:2	284:23 285:25	Delicato 161:21
134:11 142:21	12:7 13:10 14:2,3	302:12 303:22	265:25 270:7	236:12 Dell'anta 161-21
110:20 111:13	7:24 10:25 11:22	285:13 297:12	132:11 143:13	230:23 231:1,24
102:8 110:12,13	4:21,21 5:9,18	278:21 282:1	100:18 127:18,25	deliberately 222:4
78:9 88:13,20,22	Dean 2:8,22,24 4:3	275:17 277:10	defective 98:18	127:8 293:12
database 18:24	dealings 101:4	259:15 270:16	299:23	deliberate 60:4
294:5,6,9 304:10	dealing 225:3 274:2	247:2,11 251:13	203:5 233:25	198:24,24
289:9 292:5,5	180:19	226:13 240:17	140:12,20 149:15	delay 44:18 158:19
286:19 287:25	deal 12:13 155:2	216:3 221:8 226:2	91:5,20 92:5	297:7
264:13,17 271:2	deadlines 226:18	201:5 215:18	89:8,15 90:24	279:24 286:23
196:20 211:12,12	227:15 289:5	199:6,10,14 201:4	87:21,23 88:3	degree 254:3
142:20 143:11,12	deadline 181:8	193:24 194:2	defect 86:21 87:1	217:9 231:12
134:11 137:9	DE 1:17	183:5 185:5,9,10	defaults 275:2,12	188:24 213:19
133:9,25 134:10	17:15 24:9 202:5	180:6 181:1 183:4	275:6,9	136:16 182:12
126:1,2,9 133:3,5	days 14:16,20	174:17 176:16	default 140:24	definitive 74:6,13
123:14 125:15	278:20 295:15	170:25 171:14	149:15	definitely 288:25
122:24 123:7,14	251:9 268:17	168:19 169:15	decrees 60:7	definite 171:18
102:12 122:9,14	237:13 243:9,10	167:12 168:1,5,9	173:22 245:2	defining 48:12
101:4,12,20,24	207:15 209:22	165:20 166:10,21	142:20 151:19,20	61:12 224:18
88:13,20 97:1	161:5 184:5,7,20	157:5 164:25	decree 26:12 82:4	define 46:7 48:9
data 16:13 18:2,24	149:15 158:10	145:25 146:9,11	241:10	deficient 161:8
173:1 176:10 dashboards 211:13	day 13:12 27:21 44:4 65:5 91:18	144:25 145:2,13	declined 55:23	233:14 280:22
		142:11 144:1,15	decline 56:9 151:21	164:19 172:13

Videotaped

June 30, 2010

			·····	rage 317
dependent 82:15	156:17 170:9	3:20 4:8 17:20,24	265:19 274:12,19	221:4 236:11,22
deposition 1:10 4:6	205:9 234:2	17:24 18:2,10,14	digress 142:6	244:16,19,25
5:19,22 6:5 7:7	249:11 266:25	18:16,19,22,25	diligence 83:19	252:1 277:6,19,19
8:2,4,24 9:7 12:9	267:4 270:2 288:8	19:3,5 22:22 30:4	85:6 123:11	277:21 278:8
13:6,16,21 16:21	determination	41:20 62:12,15,23	149:22 154:16	289:9,11 295:6
17:4 20:22 21:12	166:3 225:15	63:3,11 70:15	155:9,11 289:4	discredibility
25:20 29:19 38:21	246:7 270:12	72:20 73:23 77:8	diligent 68:16	231:10
38:24 39:12,13,23	284:11	82:14 83:17 86:2	dinner 300:2	discuss 15:16 74:10
40:1,1 67:25	determine 56:8	86:5,20 90:17	direct 14:14 105:24	175:25 254:10
68:20 90:11	93:23 118:1	91:12,19,20 92:4	106:18 129:9	discussed 15:17
127:21 238:3	213:14 220:17	102:18 115:6,22	131:9 133:20	24:21 138:19
239:19 240:16	252:5 253:3	116:4 117:16,21	148:9 200:25	139:15 177:2
254:19 288:21	determined 11:9	121:24 122:6	201:17 233:8,17	225:7 251:12
289:1 302:17	118:21 269:20	123:23 126:20,23	262:4	discussing 117:16
306:6,10 307:6	determines 89:23	127:18,25 128:4	directed 64:6	138:18
depositions 15:20	develop 56:14,14	131:22 135:20	131:12 269:4,12	discussion 11:17
17:13,14 194:11	develops 298:10	137:7 139:18	281:9	16:4 52:15 55:8
293:12,14	deviation 61:2	141:20 143:23	direction 6:17 18:4	104:21 129:17
described 76:15	dialogue 210:23	144:8 147:1	85:18 181:19	146:1 181:10
110:5 188:6	236:1 237:15	152:24 153:11,18	230:25 249:6	199:2 233:13
201:13	Dianna 1:14 4:16	156:9,11,14,17,23	directions 33:3	234:3 247:7
descriptors 305:1	Dick 53:12 72:15	156:25 157:7,13	directly 137:25	285:19
destroy 238:5	296:6	157:13 160:6	202:20,21 262:2	discussions 56:11
destroyed 147:24	difference 10:3	185:22,25 186:2,3	265:7	diseases 216:14
destruction 146:19	199:15	186:15 191:4,13	disagree 108:5	disks 32:13
147:22	differences 301:3	192:21 193:3,19	132:7,17 165:21	display 225:2,3
detail 49:16 74:22	different 40:21,22	194:8,12,19 195:3	167:23	disputes 96:20
80:20 84:9 96:15	47:17 86:15 118:8	231:4 233:17	discard 292:8	disseminated 289:9
detailed 198:21	152:25 167:21	249:11 260:23	discarded 229:25	distant 300:15
204:24 205:2	191:15 202:5,17	262:2,4,10 263:1	discern 301:24	distilled 178:13
details 14:5 246:9	215:16 230:20	265:7,11,19	disclosed 239:18,24	200:18
detect 88:14	271:18 291:10	266:14,24 267:13	241:5 242:6 244:9	distracted 132:21
detected 136:25	differing 288:5	268:2 269:19	267:20 305:4	distributed 87:14
154:16	difficult 81:12	272:5,19,22	disclosure 242:7	118:7 119:15
detection 70:14,19	166:25 273:25	276:12 284:24	disconcerting	distributes 148:15
73:25 74:25 82:13	274:17 298:19,25	286:1 288:5	136:11	149:1
83:16 84:6 86:1	301:2,15 303:12	297:24 298:2	disconnection	distributing 260:21
87:1,5,20 90:5	difficulties 300:20	299:1,22 300:11	11:14	distribution 88:17
91:21 92:4 93:18	difficulty 304:9	300:19 301:24	discordance 114:16	89:3 188:13
93:22 101:25	digitalis 139:21,22	302:6	discovered 236:10	District 1:1,1 4:9,9
102:5,9 117:15	139:22 273:21,22	digitoxicity 139:20	discovery 7:16	107:6,9 164:17
118:18 129:12	274:2,5,21 297:22	Digoxin 119:10	23:10 26:1 29:10	167:9 182:15
131:13,14,20	298:6,13,15 299:8	126:19 157:12	52:13,14,16 85:10	280:20
135:23 136:7,20	299:8	193:18,21,22	85:11,12 154:9	division 1:2 4:10
140:1,6,11,20	Digitek 1:5 3:3,15	194:4,6,11,18	179:1 220:19	94:20 122:15
		1		
Established and the second of	Anaztara			Nan-A

Videotaped

June 30, 2010

divisions 97:8 doctor 13:4 23:7 256:14 269:11 127:3,12 132:20 119:7,23 120:19 95:17,22,25 100:17 110:4 doctor 13:4 23:7 27:2,11 74:3 222:18 276:17 13:2,23 136:14 276:12 doubt 131:24 100:17 110:4 100:12 10:1 100					
doctor 13:4 23:7 71:2,11 74:3 272:18 276:17 132:23 136:14 276:12 100:17 110-4 127:7 136:16 197:9 206:16 documentary 125:3 151:6 160:19 167:16 174:7 doubts 239:2 doubts 239:2 140:9 148:25 150:22 164:18 167:16 174:7 doubts 239:2 doubts 239:2 140:9 148:25 150:22 164:18 150:22 164:18 167:16 174:7 doubts 239:2 download 22:19 download 22:19 download 22:19 download 22:19 150:22 164:18 150:22 164:18 150:22 164:18 150:22 164:18 197:16,16,18,19 250:22 161:22:19 250:24 257:22 252:42 257:22 252:42 257:22 252:42 257:22 252:42 257:22 252:42 257:22 270:23 277:20,21 <td>divisions 97.8</td> <td>256:14 269:11</td> <td>127:3.12 132:20</td> <td>119:7.23 120:19</td> <td>95:17,22,25</td>	divisions 97.8	256:14 269:11	127:3.12 132:20	119:7.23 120:19	95:17,22,25
71:2,1174:3 197:9 206:16 197:9 206:16 268:24 272:3 294:11 2034:254:4 268:24 272:3 294:11 2034:274:5 190:22 191:22 2034:274:5 190:22 191:22 2034:274:5 190:22 191:22 203:41 21:22:12 203:41 21:22:12 203:42 272:3 29:211,17,22 10:1 10:12,16,17 11:8 236:18 303:1 222:12 235:16 236:18 303:1 27:23 18:6 23:20 24:8 26:6,22 2108:25 136:22 248:28 26:6,22 2108:25 136:22 248:14 49:1,20 250:22 12:12 250:22 12:12 250:22 12:12 250:22 12:12 250:22 12:12 250:22 12:12 250:22 12:12 250:23 26:25 250:22 50:25 50:25 260:21 200:24 260:24 21:16; 270:23 21:12 270:24 21:21 270:34 27:7 260:24 12:12 270:34 27:7 270:34			•	•	* * *
197:9 206:16 233:4 254:4 254:2 210:8 210:8 210:8 210:8 210:8 210:9 167:16 174:7 20:4 217:2 20:2 20:2 20:2 20:2 20:2 20:4 20:4 20:5 20:2 20:2 20:4 20:4 20:5 20:2 20:2 20:4 20:4 20:4 20:5 20:2 20:2 20:4 20:4 20:4 20:5 20:2 20:2 20:4 20:4 20:4 20:5 20:4 20:4 20:4 20:4 20:4 20:4 20:4 20:4				doubt 131:24	127:7 136:16
233:4 254:4 268:24 272:3 294:11 doctors 202:14,21 203:4 274:5 199:22 191:22 235:11,23,24,25 190:22 191:22 235:16,21,17,22 10:1 10:12,16,17 11:8 236:18 303:1 222:12 235:16 221:1,23,24,25 17:23 18:6 23:20 24:8 26:6,22 28:8 26:6,22 28:8 26:6,22 28:8 26:6,22 28:8 26:6,22 28:8 26:6,22 28:3 30:18 31:20 32:12 33:19 34:5 34:16,21 35:11 36:18 42:8 46:11 48:14 49:1,20 50:22 17:23 20:24 18:11 172:7 18:11 27:15 18:11 172:7 18:11 172:7 18:11 172:7 18:11 173:17,19,22 20:12 23:11 21:24 17:10:12 21:2 16:1 22:12 21:24 17:20 23:3 26:2,5 100:11 17:25 11:1 21:21 17:16 23:16,21 32:11 21:21 17:16 23:16,21 32:11 21:21 17:16 23:16,21 32:11 23:11 134:16 137:19 139:9 140:18 145:21 146:1,5 147:12 152:16 159:17 167:22 170:12,17 160:10 10:23,16 10:17,21 18:2 10:20:24 212:19 203:4 27:22 200:24 20:24 203:4 27:23 200:24 20:24 203:4 27:23 200:24 20:24 203:4 27:23 200:24 20:24 203:10 203:4 27:4 203:4 27:5 200:21 20:14 203:4 27:5 200:21 20:14 203:4 27:5 200:22 60:14 203:4 27:5 200:22 60:14 203:4 27:5 200:22 60:14 203:4 27:5 200:22 60:14 203:4 27:5 200:22 60:14 203:4 27:5 200:22 60:14 203:4 27:5 200:22 60:14 203:4 27:5 200:22 60:14 203:4 27:5 200:22 60:14 203:4 27:5 200:22 120:12 200:12 20:14 203:4 27:5 200:22 120:12 200:12 20:14 200:22 120:12 200:12 20:14 200:22 120:12 200:12 20:14 200:22 120:12 200:12 20:14 200:22 120:12 200:12 20:14 200:22 120:12 200:22 20:23 20:25 200:22 60:14 200:22 20:23 20:25 200:22 20:24 20:22 200:22 20:24 20:22 200:22 20:24 20:22 200:22 20:24 20:22 200:22 20:24 20:22 200:22 20:24 20:22 200:22 20:24 20:22 200:22 20:24 20:22 200:22 20:24 20:22 200:22 20:24 20:22 200:22 20:24 20:22 200:22 20:24 20:22 200:22 20:24 20:22 200:22 20:24 20:22 200:22 20:24 20:22 200:24 20:24 200:24 20:21 203:14 24:21 24:7 203:17:24 20:25 200:22 20:22 20:22 200:22 20:22 20:22 200:22 20:22 20:22 200:22 20:22 20:22 200:22 20:22 20:22 200:22 20:22 20:22 200:22 20:22 20:22 200:22 20:22 20:22 20:22 200:22 20:22	1 '		•		140:9 148:25
182:2 183:19 209:14 210:9 210:22 217:210:14,19 202:17 20:18 209:12 200:12 249:12 249:12 249:12 249:12 27:21,12 230:24 27:21,12 230:24 27:21,12 230:24 27:21,12 230:24 27:21,12 230:14 27:21,12 230:14 27:12,12 230:14 27:12,14 27:14 27:14 27:14 27:14 27:14 27:14 27:14 27:14 27:14		_		· ·	150:22 164:18
294:11 119:14 138:4	i I				197:16,16,18,19
doctors 202:14,21 203:4 274:5 document 8:18,23 9:2,11,17,22 10:1 10:12,16,17 11:8 236:18 303:1 12:1,15,24 13:22 10:235:16 22:12 235:16 22:12 235:16 236:18 303:1 20:17:23 18:6 23:20 108:25 136:22 108:25 136:22 108:25 136:22 108:25 136:22 108:25 136:22 108:25 136:22 108:25 136:22 108:25 136:22 108:25 136:22 108:25 136:22 108:25 136:22 108:25 136:22 108:25 136:23 17 documenting 27:9 108:10 298:7 documents 3:11 222:16:12 22:12 20:16:15 22:12 20:16:15 22:12 20:16:15 22:12 20:16:15 23:11 30:16 20:11 30:16 10:23,16 215:8 217:7 23:17 23:11 25:8,56 10:5 20:17:25 17:19,25 17:6 48:14 49:1,20 10:16 10:23,16 215:8 217:7 23:17 23:17 23:17 23:17 23:17 23:17 23:17 23:17 23:18 23:16,18 30:31 20:18 31:10 134:16 13:19 13:19 29 13:19	1 1				202:17 210:14,19
203.4 274.5 document 8:18,23 documented 10:13 236:18 303:1 documented 10:13 25:4 277:20,21 17:23 18:6 23:20 28:23 30:18 31:20 151:25 159:18,20 23:12 33:19 34:5 24:66:1 27:32 29:6 23:108:25 136:22 23:10 32:13 31:9 34:5 24:6 21 33:19 34:5 25:4 257:22 28:23 30:18 31:20 151:25 159:18,20 32:13 31:9 34:5 24:6 21 33:19 34:5 36:18 42:8 46:11 48:14 49:1,20 documenting 27:9 108:15 277:22 59:22 60:11 66:3 documents 3:11 75:25 77:18 22:14,17,20 23:3 85:15 92:9 104:3 23:16,13 11:1 22: 16: 15 22:12 27:24 75:5 77:18 22:14,17,20 23:3 85:15 92:9 104:3 23:16,13 11:1 22: 16: 15 22:12 22:14,17,20 23:3 13:10 134:16 38:10,62,021 124:21 127:16 130:25 33:13 36:25 38:6 130:13 136:21 32:11 130:25 131:10 134:16 38:10,62,021 124:11 130:25 131:10 134:16 38:10,62,021 124:11 130:25 131:13,13,22 14:15 25:6,17,22 164:13,166:19 53:8,21 56:4,4,15 166:12,21 120:12 106:14 137:19 139:9 42:7 43:13 44:5 166:12,17 167:22 170:12,17 56:17,21 57:17 138:12 184:1 190:4 199:22 66:1 67:7,21 74:8 190:4 199:22 66:1 67:7,21 74:8 190:4 199:22 66:1 67:7,21 74:8 190:4 199:22 66:1 67:7,21 74:8 190:4 199:22 66:1 67:7,21 74:8 190:4 199:22 66:1 67:7,21 74:8 190:4 199:22 66:1 67:7,21 74:8 190:4 199:22 66:1 67:7,21 74:8 190:4 199:22 66:1 67:7,21 74:8 190:4 199:22 66:1 67:7,21 74:8 190:4 199:22 66:1 67:7,21 74:8 190:4 199:22 66:1 67:7,21 74:8 190:4 199:22 66:1 67:7,21 74:8 190:4 199:22 66:1 67:7,21 74:8 190:4 199:22 66:1 67:7,21 74:8 190:4 190:2 211:1 120:1 14 10:16 102:3,16 10:16 102:3,16 10:16 102:3,16 10:16 102:3,16 10:16 102:3,16 10:16 102:3,16 10:16 102:3,16 10:13 10:16 102:3,16 10:16 102:3,16 10:16 102:3,16 10:16 102:3,16 10:16 102:3,16 10:16 10:2,3 10 10:16 102:3,16 10:16 10:2,3 10 10:16 102:3,16 10:16 10:2,3 10 10:16	· · · · · · · · · · · · · · · · · ·			dozen 120:12	210:24 212:19
document 8:18,23 9:2,11,17,22 10:1 134:9 209:14 236:19 237:14 5:15,17 9:23 11:5 280:21 292:7 299:6 299:6 drug files 4 5:15,17 9:23 11:5 280:21 292:7 299:6 4 280:21 292:7 299:6 4 280:21 292:7 299:6 4 280:21 20:2 299:6 4 280:21 292:7 299:6 4 280:21 20:2 22:2:4 257:22 299:6 4 280:21 20:2 22:2:4 257:22 20:2:2 30:24 4 29:2:3 3:14 3 22:2:2:2 23:22 22:2:2:2 23:22 22:2:2:2 23:22 22:2:2:2 23:22 22:2:2:2 23:22 22:2:2:2 22:2:2:3 23:23 3 6:1 71:4 92:22 22:2:2 23:22 22:2:2:3 23:23 3 6:1 71:4 92:22 22:2:2 30:24 40:9:23 45:12 3 36:16 95:18 97:11 36:16 95:18 97:11 39:14:19 129:23 33:17:14 48:21 40:23 3:17 36:16 93:14 40:9:23 45:12 40:23 37:14 40:9:23 45:12 40:23 37:14 40:9:23 45:12 40:23 32:23:11 30:14:18 40:23 32:13 36:16 92:34:18 40:23 40:21 40:23 40:21 40:23 40:21 40:23 40:21 40:21 40:21 40:21 40:21 </td <td>•</td> <td></td> <td></td> <td>· ·</td> <td>265:15 274:19,25</td>	•			· ·	265:15 274:19,25
9:2,11,17,22 10:1 10:12,16,17 11:8 12:1,15,24 13:22 17:23 18:6 23:20 24:8 26:6,22 28:23 30:18 31:20 31:18 31:20 32:12 33:19 34:5 34:16,21 35:11 36:18 42:8 46:11 48:14 49:1,20 50:22 51:2 57:22 59:22 60:11 66:3 67:3,3,11,13,15 71:13,17,19,22 72:4 75:5 77:18 85:15 92:9 104:3 109:12 23:11 24:21 127:16 109:12 23:11 24:21 127:16 109:13 39:9 140:18 145:21 120:13 31:9 130:25 130:23 130:14:19 120:25 130:14:19 120:25 130:25 130:25 130:25 130:24 121:48:7 121:16,20 16:24 19:8 22:2 26:22 27:21,22 30:24 40:9,23 45:12 130:37 43:12 14:15 251:11 24:21 25:11 24:21 25:12 220:22 228:20 23:12 40:9,23 45:12 130:37 47:18 77:7 220:23 130:37 40:9,23 45:12 130:37 41:15 20:11 24:20 47:02:37:26 140:8,11 208:11 298:7 25:24 27:25 27:21,22 30:24 40:9,23 45:12 130:74 14:15 251:11 26:24 70:23 72:6 27:12,23 0:24 27:21,22 30:24 27:21,2 30:24 27:21,2 30:24 27:21,2 30:24 27:21,2 30:24 27:21,2 30:24 27:21,2 30:24 27:21,2 30:24 27:21,2 30:24 27:21,2 30:24 27:21,2 30:24 27:	·		, , , , , , , , , , , , , , , , , , ,		280:21 292:7
10:12,16,17 11:8 12:1,15,24 13:22 17:23 18:6 23:20 24:8 26:6,22 28:23 30:18 31:20 32:12 33:19 34:5 32:13 19:34:5 32:13 11:20 32:13 19:34:5 32:13 19:34:5 32:13 19:34:5 32:13 19:34:5 32:13 19:34:5 32:13 19:34:5 32:13 19:34:5 32:13 19:34:5 32:13 11:20 32:13 1	1			,	299:6
12:1,15,24 13:22 17:23 18:6 23:20 24:8 26:6,22 24:8 26:6,22 22 28:23 30:18 31:20 32:12 33:19 34:5 34:16,21 35:11 36:18 42:8 46:11 36:18 42:8 46:11 36:18 42:8 46:11 36:18 42:8 46:11 36:18 42:8 46:11 36:18 42:8 46:11 36:18 42:8 46:11 36:18 42:8 46:11 36:13 17:7 36:18 42:8 46:11 36:18 17:7 36:18 42:8 46:11 36:19 51:8 20:2 323 27:23 27:2,2 32:2 323 28:14 39:6,8 323 45:12 32:2 345:12 32:2 345:12 32:2 345:12 32:2 345:12 32:2 345:12 32:2 345:12 32:3 45:12 32:3 45:12 32:3 45:12 32:3 45:12 32:3 45:12 32:3 45:12 32:3 45:12 32:3 45:12 32:3 45:12 32:3 45:12 32:3 45:12 32:3 45:12 32:3 45:12 32:3 45:12 32:3 45:12 32:3 45:12 32:3 45:12 32:4 60:21 32:3 45:12 32:4 40:9,23 45:12 32:3 45:12 32:4 5:2 40:23 32:3 45:12 32:3 45:12 32:3 45:12 32:3 45:12 32:3 45:12 32:3 45:12 32:3 45:12 32:3 45:12 32:3 45:12 32:3 45:12 32:3 45:12 32:18 47:13 32:11 40:21 32:3 79:24 32:3 23:13 148:2 32:3 23:13 148:2 33:1 48:13 32:1 148:2 33:1 148:2 33:1 148:2 33:1 148:2 33:1 148:2 33:1 148:2 33:1 148:2 33:1 148:2 33:1 148:2 33:1 148:2 33:1 148:2 33:1 148:2 33:1 148:2 33:1 148:2 33:1 148:2 33:1 148:1 33:1 1			Y .		drugs 16:5 61:13
280:8					•
24:8 26:6,22 28:23 30:18 31:20 32:12 33:19 34:5 31:10 33:19 34:5 31:10 33:19 34:5 31:10 33:19 34:5 31:10 33:19 34:5 31:10 33:11 36:11 172:7 34:16,21 35:11 36:18 42:8 46:11 48:14 49:1,20 50:22 51:2 57:22 50:22 60:11 66:3 60cuments 3:11 7:15 81:5,6 10:5 71:13,17,19,22 72:4 75:5 77:18 82:14,17,20 23:3 85:15 92:9 104:3 23:16,18 24:2,6 104:17 106:1 25:22,23 26:2,5 107:2 108:10 29:19 30:9 31:4 109:2 123:11 131:10 134:16 139:17 140:3 140:9,23 45:12 64:24 70:23 72:6 64:24 70:3 73:6 73:6 74:18 75:7 75:18 77:12,20 83:7 84:8,13 85:19 121:19,21 137:1 149:2 278:8 256:23 137:1 148:20 166:18,21 168:20 128:11 149:22 120:12 16:1 22:12 130:29 304:21 191:2 204:16 123:11 149:22 123:11 226:14 129:1 130:25 35:18 36:25 38:6 131:10 134:16 38:10,16,20,21 137:19 139:9 42:7 43:13 44:5 140:18 145:21 146:15, 147:12 152:16 159:17 163:12,13,22 164:1,3 166:19 51:15 52:6,17,22 164:1,3 166:19 51:15 52:6,17,22 164:1,3 166:19 51:15 52:6,17,21 56:17,21 57:17 183:12 184:1 190:4 199:22 200:21 206:14 200:21 206:14 200:21 206:14 200:22 170:12,17 183:12 184:1 190:4 199:22 200:21 206:14 200:23 25:14 200:22 32:3 25:14 200:21 206:14 200:23 25:14 200:21 206:14 200:23 25:14 200:21 206:14 200:23 25:14 200:21 206:14 200:21 206:14 200:23 25:14 200:21 206:14 200:23 25:14 200:21 206:14 200:23 25:14 200:21 206:14 200:23 25:14 200:21 206:14 200:23 25:14 200:21 206:14 200:23 25:14 200:21 206:14 200:23 25:14 200:21 206:14 206:22 3 25:14 200:20 20:21 206:14 200:22 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2			· · · · · · · · · · · · · · · · · · ·	,	97:14,19 129:23
28:23 30:18 31:20 32:12 33:19 34:5 34:16,21 35:11 36:18 42:8 46:11 48:14 49:1,20 50:22 51:2 57:22 59:22 60:11 66:3 67:3,31,1,3,15 7:15 8:5,6 10:5 71:13,17,19,22 72:4 75:5 77:18 82:14,17,20 23:3 85:15 92:9 104:3 107:2 108:10 108:17 109:12 109:2 120:1:1 109:2 120:1:1 109:2 120:1:1 109:2 120:1:1 109:2 120:1:1 109:2 120:1:1 109:2 120:1:1 100:2 108:10 108:17 11:11:19:1 109:2 120:1:1 109:2 120:1:1 109:2 120:1:1 109:2 120:1:1 109:2 120:1:1 100:2 108:1 109:2 120:1:1 100:2 108:10 108:18 3:19 12:1:19:1 108:18 7:10 7:18 85:19 12:1:19,21 108:18 7:10 7:18 7:12 108:18 7:10 7:18 7:12 1				,	139:17 140:3
32:12 33:19 34:5 34:16,21 35:11 36:18 42:8 46:11 48:14 49:1,20 50:22 51:2 57:22 50:22 51:2 57:22 50:22 51:2 57:18 60cuments 3:11 7:15 8:5,6 10:5 71:13,17,19,22 72:4 75:5 77:18 85:15 92:9 104:3 104:17 106:1 22:14,17,20 23:3 85:15 92:9 104:3 109:2 123:11 124:21 127:16 109:2 123:11 124:21 127:16 137:19 139:9 140:18 145:21 146:1,5 147:12 152:16 159:17 163:12,13,22 164:1,3 166:19 167:22 170:12,17 183:12 184:1 190:4 199:22 200:21 206:14 208:12 209:21 206:14 208:12 200:21 206:21 200:21 206:14 208:12 200:21 206:21 200:21 206:14 208:12 200:21 206:21 200:21 206:14 208:12 200:21 206:21 200:21 206:21 200:21 206:21 200:21 206:21 200:21 206:21 200:21 206:21 200:21 2	1	· · · · · · · · · · · · · · · · · · ·			141:15 251:11
34:16,21 35:11 36:18 42:8 46:11 48:14 49:1,20 50:22 51:25 7:22 50:21 60:11 66:3 67:3,3,11,13,15 71:13,17,19,22 72:4 75:5 77:18 85:15 92:9 104:3 108:15 109:17 273:20 108:15 100:15 85,6 10:5 12:2 16:1 22:12 12:2 16:1 22:12 12:2 16:1 22:12 100:15 92:14,17,20 23:3 23:16,18 24:2,6 104:17 106:1 107:2 108:10 109:2 123:11 124:21 127:16 129:1 30:25 131:10 134:16 137:19 139:9 140:3,11 208:11 124:21 127:16 137:19 139:9 140:3,11 208:11 124:21 127:16 137:19 139:9 140:3,11 208:11 140:3,11 208:11 140:3,11 208:11 140:3,11 208:11 140:3,11 208:11 140:3,11 208:11 140:3,11 208:11 140:3,11 208:11 140:3,11 208:11 122:28 228:20 239:7,9 245:13 253:8 256:23 137:1 148:2 166:18,21 168:20 180:7 183:1,6,25 191:2 204:16 180:18,18 190:2 204:16 180:18 145:21 160:18,21 16:19 160:18,21 16:19 160:18,21 16:20 180:7 183:1,6,25 191:2 204:16 180:7 183:1,6,25 191:2 204:16 180:7 183:1,6,25 191:2 204:16 180:7 183:1,6,25 199:2 24:11 226:14 244:1 226:14 244:1 226:14 244:1 226:14 244:1 226:14 244:1 226:14 244:1 226:14 245:5 247:15 283:10 48:14 8:16 40use 30:19 85:6 123:11 148:2 154:16 155:9,11 299:23 40ullars 26:15 206:21 209:24 40use 30:19 85:6 4ue 83:19 85:6 123:11 148:2 154:16 155:9,11 299:23 40ullars 26:15 244:11 226:14 48:16 40use 30:19 85:6 4ue 83:19 85:			·		264:24 265:20
36:18 42:8 46:11 48:14 49:1,20 50:22 51:2 57:22 59:22 60:11 66:3 67:3,3,11,13,15 7:15 8:5,6 10:5 71:13,17,19,22 72:4 75:5 77:18 85:15 92:9 104:3 85:15 92:9 104:3 104:17 106:1 109:2 123:11 131:0 134:16 137:19 139:9 140:18 145:21 146:1,5 147:12 146:1,5 147:12 152:16 159:17 163:12,13,22 164:1,3 166:19 165:17,25 76:17 183:12 184:1 190:4 199:22 200:21 206:14 208:1 209:5 211:1 208:15 228:8 228:20 239:7,9 245:13 253:8 256:23 258:17 266:20 258:17 296:12 258:17 296:12 295:17 296:12 295:17 296:12 180:7 188:1,6,25 191:2 204:16 299:23 302:9 304:21 191:2 204:16 206:21 209:24 206:21 209:24 206:21 209:24 206:21 209:24 206:21 209:24 206:21 209:24 206:21 209:24 206:21 209:24 206:21 209:24 206:21 209:24 206:21 208:2 273:23 283:10 287:15 Duces 67:25 due 83:19 85:6 123:11 149:22 166:18,21 168:20 180:7 183:1,6,25 191:2 204:16 206:21 209:24 206:21 209:24 206:21 209:24 206:21 209:24 206:21 209:24 206:21 208:2 273:23 285:15 206:21 209:24 206:21 209:24 206:21 209:24 206:21 209:24 206:21 209:24 206:21 209:24 206:21 209:24 206:21 209:24 206:21 209:24 206:21 209:24 206:21 208:2 273:23 206:21 209:24 206:21 209:24 206:21 208:2 273:23 206:21 209:24 206:21 209:24 206:21 208:2 273:23 206:21 209:24 206:21 209:24 206:21 208:2 273:23 287:15 Duces 67:25 due 83:19 85:6 123:11 149:22 154:16 155:9,11 299:23 244:11 226:14 224:11 226:14 224:11 226:14 224:11 226:14 224:12 206:14 224:12 208:2 273:23 285:15 206:21 209:24 206:21 208:2 273:23 206:21 208:2 273:23 206:21 208:2 273:23 206:21 208:2 206:21 209:24 206:21 209:24 206:21 209:24 206:21 209:24 206:21 208:2 273:23 242:1 226:14 25:14,70,0 23:3 26:25 26:25 26:25 26:25 26:25 26:25 26:25 26:25 273:25 26:25 26:25 26:25 273:25 26:25 273:23 28:10 24:25 247:15 29:51 45:16 29:51 45:16 29:51 45:16 206:21 209:24 245:5 247:15 245:5 247:15 242:12 120:14 24:21 127:16 24:21 127:16 24:21 127:16 24:21 127:16 24:21 127:16 25:14:41 25:14:41 126:14 25:14:41 126:14 25:14:41 126:14 25:14:41 126:14 224:11 226:14 224:12 226:14 224:12 226:14 225:14:10 225:14:10 25:14:10 25:14:10 25:14:10 25:14:10 25:14:10 25:14:10 25:14:10 25:				75:18 77:12,20	268:2 272:5
48:14 49:1,20 50:22 51:2 57:22 59:22 60:11 66:3 67:3,3,11,13,15 71:13,17,19,22 72:4 75:5 77:18 85:15 92:9 104:3 104:17 106:1 109:2 123:11 124:21 127:16 131:10 134:16 137:19 139:9 146:1,5 147:12 146:1,5 147:12 152:16 159:17 153:12 184:1 190:4 199:22 108:15 108:15 108:15 108:15 108:15 239:7,9 245:13 253:8 256:23 258:17 261:20 295:17 296:12 302:9 304:21 302:9 304:21 302:9 304:21 302:9 304:21 302:9 304:21 302:9 304:21 302:11 19:2 204:16 299:23 40ly 5:6 40ties 94:16 40ties			·	l '	287:15
50:22 51:2 57:22 108:15 253:8 256:23 137:1 148:2 due 83:19 85:6 59:22 60:11 66:3 253:8 256:23 137:1 148:2 137:1 148:2 137:1 148:2 67:3,3,11,3,15 71:13,17,19,22 12:2 16:1 22:12 295:17 296:12 180:7 183:1,6,25 154:16 155:9,11 71:13,17,19,22 12:2 16:1 22:12 302:9 304:21 191:2 204:16 299:23 85:15 92:9 104:3 23:16,18 24:2,6 23:16,18 24:2,6 23:16,18 24:2,6 206:21 209:24 299:23 107:2 108:10 29:19 30:9 31:4 304:18,18 224:11 226:14 229:13 23:5:15 224:11 226:14 29:19 30:9 31:4 23:23 235:15 224:11 226:14 224:11 226:14 225:2,23 26:2,5 23:16,18 24:2,6 23:16,18 24:2,6 23:11 11 119:9 245:5 247:15 225:145:9 225:1	1 ' '			•	Duces 67:25
59:22 60:11 66:3 documents 3:11 258:17 261:20 166:18,21 168:20 123:11 149:22 67:3,3,11,3,15 7:15 8:5,6 10:5 295:17 296:12 302:9 304:21 191:2 204:16 299:23 72:4 75:5 77:18 22:14,17,20 23:3 22:14,17,20 23:3 23:16,18 24:2,6 206:21 209:24 201:2 20	•	_	·	137:1 148:2	due 83:19 85:6
67:3,3,11,13,15 7:15 8:5,6 10:5 71:13,17,19,22 72:4 75:5 77:18 85:15 92:9 104:3 104:17 106:1 107:2 108:10 109:2 123:11 124:21 127:16 139:1 30:25 13:10 134:16 137:19 139:9 140:18 145:21 146:1,5 147:12 152:16 159:17 163:12,13,22 164:1,3 166:19 167:22 170:12,17 183:12 184:1 190:4 199:22 200:21 206:14 205:17 296:12 302:9 304:21 302:9 304:21 302:9 304:21 302:9 304:21 302:9 304:21 302:9 304:21 302:9 304:21 302:9 304:18,18 224:11 226:14 224:11 226:14 232:3 235:15 245:5 247:15 245:5 247:15 245:5 247:15 245:5 247:15 245:5 247:15 245:5 247:15 245:5 247:15 245:10 119:2 204:16 240:21 209:24 24:11 226:14 232:3 235:15 245:5 247:15 245:5 247:15 245:5 247:15 245:5 247:15 245:5 247:15 245:10 119:2 204:16 240:21 209:24 24:11 226:14 24:11 226:14 24:12 126:14 24:11 19:9 245:5 247:15 245:5 247:15 245:5 247:15 245:5 247:15 245:5 247:15 245:5 247:15 245:5 247:15 245:10 119:2 204:16 240:21 209:24 24:11 226:14 24:11 226:14 24:12 26:14 25:24:11 226:14 25:24:11 226:14 24:11 226:14 24:11 226:14 24:12 20:14 24:11 226:14 25:24:11 226:14 24:12 26:14 24:13 120:49:23 24:11 226:14 25:24:11 226:14 25:24:11 226:14 25:24:11 226:14 25:24:11 226:14 24:11 226:14 24:11 226:14 24:11 226:14 25:24:11 226:14 25:24:11 226:14 23:3 235:15 245:5 247:15 245:5 247:15 245:5 247:15 245:5 247:15 245:5 247:15 245:10 119:2 204:16 24:11 226:14 24:12 24:11 226:14 24:12 24:11 226:14 24:12 26:14 24:1			1	166:18,21 168:20	123:11 149:22
71:13,17,19,22 72:4 75:5 77:18 71:13,17,19,22 72:4 75:5 77:18 72:4 71:10:11 72:10:10 72:106:11 72:106:11 72:106:11 72:106:12 72:2 106:12 72:4 71:10 72:106:12 72:4 71:10 72:106:12 72:4 71:10				·	154:16 155:9,11
72:4 75:5 77:18 22:14,17,20 23:3 dollars 261:5 206:21 209:24 duly 5:6 85:15 92:9 104:3 23:16,18 24:2,6 304:18,18 224:11 226:14 224:11 226:14 224:11 226:14 224:11 226:14 224:11 226:14 224:11 226:14 224:11 226:14 224:11 226:14 224:11 226:14 224:15 247:15 225:14 5:9 225:14 5:9 225:14 5:9 225:14 5:9 225:14 5:9 225:14 5:9 225:15 5:11 225:15 5:10,11 225:15 5:10,11 225:15 5:10,11 225:15 5:10,11 225:15 5:10,11 225:15 5:10,11 225:15 5:10,11 2		1 *	1	, ,	299:23
85:15 92:9 104:3 23:16,18 24:2,6 304:18,18 224:11 226:14 duties 94:16 104:17 106:1 25:22,23 26:2,5 dosage 207:19 232:3 235:15 duty 148:16 109:2 123:11 31:16,21 32:11 31:16,21 32:11 245:5 247:15 D-250 45:9 109:2 123:11 31:16,21 32:11 33:21 34:1,7,14 232:3 23 23:310 D-251 45:9 124:21 127:16 33:21 34:1,7,14 33:21 34:1,7,14 33:21 34:1,7,14 33:21 34:1,7,14 33:21 34:1,7,14 33:21 34:1,7,14 33:10 D-251 45:9 D-252 47:24 D-255 53:17 D-255 55:4 D-255 53:17 D-256 65:4 D-257 58:8 D-257 58:8 D-259 60:13 D-259 60:13 D-259 60:13 D-259 60:1	1			206:21 209:24	duly 5:6
104:17 106:1 25:22,23 26:2,5 dosage 207:19 232:3 235:15 duty 148:16 107:2 108:10 29:19 30:9 31:4 dose 118:11 119:9 245:5 247:15 245:5 247:15 25:045:9 109:2 123:11 31:16,21 32:11 33:21 34:1,7,14 33:21 34:1,7,14 273:23 dose 204:21 208:2 283:10 dose 25:14:9 D-251 45:9 D-252 47:24 D-255 45:9 D-252 47:24 D-252 47:24 D-252 47:24 D-252 47:24 D-255 53:17 D-257 58:8 D-257 58:8 D-257 58:8 D-259 60:13 D-260 60:13 D-260 60:13 D-260 60:13 D-260 60:13 D-260 60:13				224:11 226:14	duties 94:16
107:2 108:10 29:19 30:9 31:4 dose 118:11 119:9 245:5 247:15 D-250 45:9 109:2 123:11 31:16,21 32:11 33:21 34:1,7,14 273:23 draft 34:1,20 49:23 D-251 45:9 129:1 130:25 35:18 36:25 38:6 35:18 36:25 38:6 dosing 200:11,17 56:19 95:17 D-254 47:24 131:10 134:16 38:10,16,20,21 dossier 225:16 215:10,11 D-255 53:17 137:19 139:9 42:7 43:13 44:5 dossier 225:16 242:25 243:2 D-255 53:17 140:18 145:21 46:2,5,13,18,19 dossiers 46:8 242:25 243:2 D-257 58:8 146:1,5 147:12 48:19 49:15 50:8 double 102:22 drafts 219:22 D-257 58:8 163:12,13,22 53:8,21 56:4,4,15 115:3 117:16 drive 12:5 34:24 D-260 60:13 167:22 170:12,17 56:17,21 57:17 183:12 184:1 104:7 219:20 driven 16:13 D-261 69:24 190:4 199:22 66:1 67:7,21 74:8 75:25 76:17 79:6 102:18,24 103:9 33:11,25 218:25 D-261 69:24 200:21 206:14 81:2 82:18 83:4 103:17 104:11 61:13 76:7,8 85:6 earlier 55:20 68:1 <td>l I</td> <td>•</td> <td>*</td> <td>232:3 235:15</td> <td>duty 148:16</td>	l I	•	*	232:3 235:15	duty 148:16
109:2 123:11 31:16,21 32:11 doses 204:21 208:2 283:10 D-251 45:9 124:21 127:16 33:21 34:1,7,14 33:21 34:1,7,14 33:21 34:1,7,14 33:21 34:1,7,14 4273:23 dorft 34:1,20 49:23 D-252 47:24 129:1 130:25 35:18 36:25 38:6 dosing 200:11,17 56:19 95:17 D-254 47:24 131:10 134:16 38:10,16,20,21 dossier 225:16 dossier 225:16 D-254 47:24 137:19 139:9 42:7 43:13 44:5 236:6 dossiers 46:8 242:25 243:2 D-255 53:17 140:18 145:21 46:25,13,18,19 249:13 276:24 drafts 219:22 D-257 58:8 163:12,13,22 51:15 52:6,17,22 double 102:22 draw 25:11 286:12 D-259 60:13 167:22 170:12,17 56:17,21 57:17 118:11 120:2,16 118:11 120:2,16 104:7 219:20 D-260 60:13 183:12 184:1 60:5,24 64:25 66:1 67:7,21 74:8 102:18,24 103:9 33:11,25 218:25 D-261 69:24 200:21 206:14 75:25 76:17 79:6 102:18,24 103:9 33:11,25 218:25 167:13,13 244:9 208:1 209:5 211:1 81:2 82:18 83:4 101:16 102:3,16 116:17,25 117:6,9 61:13 76:7,8 85:6 10:13 7		1 '		245:5 247:15	D-250 45:9
124:21 127:16 33:21 34:1,7,14 273:23 draft 34:1,20 49:23 D-252 47:24 129:1 130:25 35:18 36:25 38:6 dosing 200:11,17 56:19 95:17 D-254 47:24 131:10 134:16 38:10,16,20,21 dossier 225:16 215:10,11 D-255 53:17 137:19 139:9 42:7 43:13 44:5 236:6 drafting 215:8 D-256 55:4 140:18 145:21 46:2,5,13,18,19 dossiers 46:8 242:25 243:2 D-257 58:8 146:1,5 147:12 48:19 49:15 50:8 double 102:22 drafts 219:22 D-258 59:16 152:16 159:17 48:19 49:15 50:8 249:13 276:24 draw 25:11 286:12 D-259 60:13 163:12,13,22 51:15 52:6,17,22 105:4,8 108:7,13 drive 12:5 34:24 D-260 60:13 167:22 170:12,17 56:17,21 57:17 60:5,24 64:25 153:17 double-thick 62:15 driven 16:13 D-261 69:24 190:4 199:22 75:25 76:17 79:6 102:18,24 103:9 33:11,25 218:25 drug 22:3 25:14 167:13,13 244:9 208:1 209:5 211:1 81:2 82:18 83:4 101:16 102:3,16 116:17,25 117:6,9 61:13 76:7,8 85:6 61:13 76:7,8 85:6 61:13 76:7,8 85:6 61:22 61:22 <			doses 204:21 208:2	283:10	D-251 45:9
129:1 130:25 35:18 36:25 38:6 dosing 200:11,17 56:19 95:17 D-254 47:24 131:10 134:16 38:10,16,20,21 236:6 drafting 215:8 D-256 55:4 140:18 145:21 46:2,5,13,18,19 249:13 276:24 drafts 219:22 drafts 219:22 152:16 159:17 48:19 49:15 50:8 249:13 276:24 drafts 219:22 drafts 219:22 163:12,13,22 51:15 52:6,17,22 55:17,21 57:17 105:4,8 108:7,13 drive 12:5 34:24 D-256 55:4 167:22 170:12,17 56:17,21 57:17 18:11 120:2,16 drive 12:5 34:24 D-259 60:13 167:22 170:12,17 56:17,21 57:17 18:11 120:2,16 driven 16:13 driven 16:13 190:4 199:22 66:1 67:7,21 74:8 75:25 76:17 79:6 103:17 104:11 33:11,25 218:25 200:21 206:14 81:2 82:18 83:4 103:17 104:11 116:17,25 117:6,9 61:13 76:7,8 85:6 213:7 232:11,13 101:16 102:3,16 116:17,25 117:6,9 61:13 76:7,8 85:6				draft 34:1,20 49:23	D-252 47:24
131:10 134:16 38:10,16,20,21 dossier 225:16 215:10,11 D-255 53:17 137:19 139:9 42:7 43:13 44:5 236:6 dossier 225:16 242:25 243:2 D-256 55:4 140:18 145:21 46:2,5,13,18,19 46:22 47:16,17 48:19 49:15 50:8 249:13 276:24 drafts 219:22 D-258 59:16 152:16 159:17 48:19 49:15 50:8 249:13 276:24 double 102:22 draw 25:11 286:12 D-259 60:13 163:12,13,22 51:15 52:6,17,22 105:4,8 108:7,13 drive 12:5 34:24 D-260 60:13 167:22 170:12,17 56:17,21 57:17 60:5,24 64:25 118:11 120:2,16 104:7 219:20 D-261 69:24 183:12 184:1 60:5,24 64:25 66:1 67:7,21 74:8 102:18,24 103:9 33:11,25 218:25 D-261 69:24 200:21 206:14 75:25 76:17 79:6 102:18,24 103:9 33:11,25 218:25 167:13,13 244:9 208:1 209:5 211:1 81:2 82:18 83:4 103:17 104:11 61:13 76:7,8 85:6 early 49:13,23 219:22 219:22	i ·	1		56:19 95:17	D-254 47:24
137:19 139:9 42:7 43:13 44:5 236:6 drafting 215:8 D-256 55:4 140:18 145:21 46:2,5,13,18,19 46:2,5,13,18,19 46:22 47:16,17 46:22 47:16,17 48:19 49:15 50:8 drafts 219:22 D-258 59:16 152:16 159:17 48:19 49:15 50:8 double 102:22 draw 25:11 286:12 D-259 60:13 163:12,13,22 51:15 52:6,17,22 105:4,8 108:7,13 drew 34:10 D-260 60:13 167:22 170:12,17 56:17,21 57:17 118:11 120:2,16 104:7 219:20 D-261 69:24 183:12 184:1 60:5,24 64:25 66:1 67:7,21 74:8 double-thick 62:15 drives 20:17 33:9 33:11,25 218:25 200:21 206:14 75:25 76:17 79:6 102:18,24 103:9 33:11,25 218:25 drug 22:3 25:14 167:13,13 244:9 208:1 209:5 211:1 81:2 82:18 83:4 101:16 102:3,16 116:17,25 117:6,9 61:13 76:7,8 85:6 early 49:13,23	1	•	,	215:10,11	D-255 53:17
140:18 145:21 46:2,5,13,18,19 46:2,5,13,18,19 249:13 276:24 242:25 243:2 D-258 59:16 146:1,5 147:12 46:22 47:16,17 48:19 49:15 50:8 double 102:22 drafts 219:22 D-259 60:13 163:12,13,22 51:15 52:6,17,22 105:4,8 108:7,13 drew 34:10 D-260 60:13 164:1,3 166:19 53:8,21 56:4,4,15 115:3 117:16 drive 12:5 34:24 D-261 69:24 167:22 170:12,17 56:17,21 57:17 18:11 120:2,16 104:7 219:20 driven 16:13 190:4 199:22 66:1 67:7,21 74:8 66:1 67:7,21 79:6 double-thick 62:15 drives 20:17 33:9 33:11,25 218:25 200:21 206:14 75:25 76:17 79:6 103:17 104:11 33:11,25 218:25 drug 22:3 25:14 167:13,13 244:9 201:22 10:16 102:3,16 116:17,25 117:6,9 61:13 76:7,8 85:6 early 49:13,23	1	1	236:6	drafting 215:8	D-256 55:4
146:1,5 147:12 46:22 47:16,17 249:13 276:24 drafts 219:22 D-258 59:16 152:16 159:17 48:19 49:15 50:8 double 102:22 draw 25:11 286:12 D-259 60:13 163:12,13,22 51:15 52:6,17,22 105:4,8 108:7,13 drew 34:10 D-260 60:13 167:22 170:12,17 56:17,21 57:17 118:11 120:2,16 104:7 219:20 D-261 69:24 183:12 184:1 60:5,24 64:25 double-thick 62:15 driven 16:13 D-261 69:24 190:4 199:22 66:1 67:7,21 74:8 75:25 76:17 79:6 102:18,24 103:9 33:11,25 218:25 167:13,13 244:9 208:1 209:5 211:1 81:2 82:18 83:4 103:17 104:11 drug 22:3 25:14 61:13 76:7,8 85:6 213:7 232:11,13 101:16 102:3,16 116:17,25 117:6,9 61:13 76:7,8 85:6					D-257 58:8
152:16 159:17 163:12,13,22 164:1,3 166:19 167:22 170:12,17 183:12 184:1 190:4 199:22 200:21 206:14 208:1 209:5 211:1 213:7 232:11,13 48:19 49:15 50:8 51:15 50:6,17,22 105:4,8 108:7,13 115:3 117:16 118:11 120:2,16 118:11 120:2,16 153:17 double 102:22 105:4,8 108:7,13 115:3 117:16 118:11 120:2,16 153:17 double-thick 62:15 102:18,24 103:9 103:17 104:11 103:17 104:11 116:17,25 117:6,9 118:11 286:12 10-260 60:13 1				drafts 219:22	D-258 59:16
163:12,13,22 51:15 52:6,17,22 105:4,8 108:7,13 drew 34:10 D-260 60:13 164:1,3 166:19 53:8,21 56:4,4,15 115:3 117:16 drive 12:5 34:24 D-261 69:24 167:22 170:12,17 56:17,21 57:17 60:5,24 64:25 118:11 120:2,16 104:7 219:20 driven 16:13 190:4 199:22 66:1 67:7,21 74:8 75:25 76:17 79:6 double-thick 62:15 drives 20:17 33:9 33:11,25 218:25 208:1 209:5 211:1 81:2 82:18 83:4 103:17 104:11 drug 22:3 25:14 167:13,13 244:9 213:7 232:11,13 101:16 102:3,16 116:17,25 117:6,9 61:13 76:7,8 85:6 219:22				draw 25:11 286:12	D-259 60:13
164:1,3 166:19 53:8,21 56:4,4,15 115:3 117:16 drive 12:5 34:24 D-261 69:24 167:22 170:12,17 56:17,21 57:17 118:11 120:2,16 104:7 219:20 104:7 219:20 183:12 184:1 60:5,24 64:25 66:1 67:7,21 74:8 66:1 67:7,21 74:8 66:1 67:7,21 74:8 66:1 67:7,21 74:8 102:18,24 103:9 33:11,25 218:25 167:13,13 244:9 208:1 209:5 211:1 81:2 82:18 83:4 103:17 104:11 116:17,25 117:6,9 61:13 76:7,8 85:6 261:22 208:1 209:5 211:1 101:16 102:3,16 116:17,25 117:6,9 61:13 76:7,8 85:6 219:22				drew 34:10	D-260 60:13
167:22 170:12,17 56:17,21 57:17 118:11 120:2,16 104:7 219:20 E 183:12 184:1 60:5,24 64:25 66:1 67:7,21 74:8 double-thick 62:15 driven 16:13 drives 20:17 33:9 33:11,25 218:25 167:13,13 244:9 208:1 209:5 211:1 81:2 82:18 83:4 103:17 104:11 103:17 104:11 118:11 120:2,16 104:7 219:20 E earlier 55:20 68:1 167:13,13 244:9 33:11,25 218:25 drug 22:3 25:14 61:13 76:7,8 85:6 261:22 early 49:13,23 219:22	•	1		drive 12:5 34:24	D-261 69:24
183:12 184:1 190:4 199:22 200:21 206:14 208:1 209:5 211:1 213:7 232:11,13 60:5,24 64:25 66:1 67:7,21 74:8 75:25 76:17 79:6 81:2 82:18 83:4 101:16 102:3,16 153:17 double-thick 62:15 102:18,24 103:9 103:17 104:11 116:17,25 117:6,9 116:17,25 117:6,9 153:17 driven 16:13 drives 20:17 33:9 33:11,25 218:25 drug 22:3 25:14 61:13 76:7,8 85:6 219:22 early 49:13,23 219:22			§	104:7 219:20	
190:4 199:22 66:1 67:7,21 74:8 75:25 76:17 79:6 81:2 82:18 83:4 213:7 232:11,13 101:16 102:3,16 double-thick 62:15 102:18,24 103:9 103:17 104:11 101:16 102:3,16 drug 22:3 25:14 61:13 76:7,8 85:6 early 49:13,23 219:22 early 49:13,23	1	1 '	1	driven 16:13	
200:21 206:14	•			drives 20:17 33:9	
208:1 209:5 211:1 81:2 82:18 83:4 103:17 104:11 drug 22:3 25:14 213:7 232:11,13 101:16 102:3,16 116:17,25 117:6,9 61:13 76:7,8 85:6 early 49:13,23		1		33:11,25 218:25	1 '
213:7 232:11,13		· -		•	1
213.7 232.11,13		· · · · · · · · · · · · · · · · · · ·	1	1 0	
	233:3,18 239:6	103:14,22 116:7	117:18 118:9	94:20 95:11,12,15	219:22
	200.0,10 200.0	100.2., 220.,			
			•		

Videotaped

June 30, 2010

				1 490 513
ease 11:10	elucidated 66:4	198:12 284:1	206:5 207:8 208:7	227:6,10 229:3,5
easier 37:15	embarrass 69:9	entitled 53:21	209:9 215:7	230:24 234:21,25
easily 124:21 212:4	278:7	250:19 257:17	evening 15:2	236:23 237:1,4
edge 212:15	embarrassed 43:3	264:23 282:5	evenly 118:6	239:20 240:14
edition 152:6	245:22 291:21	283:10	event 18:25 76:7	245:25 246:18
effective 158:5	embarrassing 69:4	entrain 129:21	78:16 89:7 107:22	247:24 248:4,6,10
efficacy 97:4	81:6	entrained 296:20	110:5 134:8	248:21,24 249:2
139:20 200:14,17	embarrassment	entreat 166:18	135:20 137:7	251:6,11,20,23
208:3	81:11 245:14,16	entry 50:8	139:5 141:16,19	252:6 253:10,12
ego 238:24	256:11,16 258:13	epidemiology	150:15 168:23	255:6,11 256:9
eight 16:23 220:7	277:7 292:2	301:21	274:8,13 286:11	262:6,8,19,22
EIR 162:11 183:21	EMEA 88:23 113:9	equipment 61:14	300:25 301:4,5,10	263:3,3 267:7,10
184:8,17 187:11	employee 143:6	equivalent 30:20	301:11,14 302:10	276:23 277:2
233:2	178:6	113:4 118:10	events 12:24 74:24	278:5,8 279:24
either 30:10 44:2	employees 143:2	equivalents 30:22	75:8,8,9,11 76:1,3	282:17 284:1
46:11 54:13 68:20	employees 143.2 employment 258:1	Erin 106:10	76:4,9,11,13 78:6	286:7,9 288:8,17
72:10 79:3 82:14	Enclosed 36:13	err 181:19	78:8,8,14 82:11	288:22 289:14,15
87:16 88:15 114:6	encouraged 217:13	error 149:21	87:6,18 88:15	289:25 290:23
116:14 118:15	220:8 221:25	163:10 183:17	89:4 132:13 134:4	291:2,4,10,23,24
138:23 142:8	224:6 228:19	231:14	139:13 140:3,4	292:5 293:9,9,14
150:4 151:7	239:5 258:25	establish 120:1	141:14 142:23	293:18,24,24
155:21 162:10	encouraging 229:8	170:22	173:21 175:14	296:23 297:3
172:13 181:19	ended 118:5 234:16	established 167:19	188:6 210:15	299:4 301:9,11
257:3 279:25	266:10 271:20	215:5 274:20	266:1 270:9 273:1	302:20 303:5,8
281:24 284:5	engage 73:24	establishes 170:13	298:12,14 299:22	evidentiary 24:6
293:20 296:14	161:14	170:18	302:6	evolve 305:20
electrical 126:15	engaged 131:21	Establishment 7:19	eventual 155:12	exacerbation
127:2 128:13	160:17 161:7	7:22 13:2 48:10	eventually 105:24	200:15
electronic 7:17,18	236:1 237:14	73:8 149:12 152:8	238:12	exact 12:4 43:19
30:11,19,22 33:6	270:3	171:6 184:5	evidence 10:18	223:10 242:12
54:14 57:21	engagement 3:14	187:16 233:12	15:19 20:21 25:18	exactly 9:25 108:20
125:18	15:22,24 19:19	288:1,2	25:19 29:4 35:12	127:4 176:19
electronically	56:9 59:1,4	eternity 126:1	50:17 51:7 53:5	179:19
10:20 11:25 31:6	239:25	EU 210:5	60:9,20 63:13	examination 2:20
31:11,15 32:11	engaging 134:3	Euclid 2:9	71:1,13 80:18,20	5:8 145:12 247:13
49:18 138:24	engines 125:15	European 154:23	89:4 102:22 103:3	268:22 286:21
175:3	ensure 131:21	evaluate 80:22	104:6 115:1,5	297:11 302:14
173.3 Elizabeth 150:19	237:6 270:4 284:3	117:14 170:9	136:16 147:23	examine 133:8
151:5 152:22	entail 240:13	176:22	160:10 166:9	228:1 255:18
169:5,5 174:1	entire 120:17	evaluated 72:1	174:11 175:1	examined 5:7 133:2
186:24 187:12	166:19 269:16,25	evaluating 119:3	180:12,24 205:6	examining 133:5
188:2,23 211:20	279:18 280:18	evaluation 60:18	211:16,22 217:10	example 301:2
1	281:13 283:2	75:18 76:25 77:9	217:13,14,17	Excel 27:6
Ellis 2:8,12 eloquent 128:18	entirely 145:8	77:18,24 98:12	218:2,11 221:7	exchange 36:4
elucidate 142:5	entirely 145.8 entirety 45:19	136:7 161:15	223:2 224:18,24	52:20 90:6 210:4
ciuciuate 142.3	entificity 43.13	150.7 101.15	223.2 227.10,27	32.20 > 0.0 2.0.1
	<u> </u>	1	I CONTRACTOR OF THE PROPERTY O	

Videotaped

June 30, 2010

				Page 320
223:20	282:4,6 283:7	219:17 220:12,14	282:20 305:2	173:3 179:11
exchanged 93:16	284:22 285:24	222:1 226:18	expresses 283:19	183:17 207:14
93:24	exhibits 8:8 24:6	227:23 236:16	expressions 71:18	218:11 233:23
excruciating 49:16	31:19 39:13 40:1	237:16 238:14,18	extend 224:5	235:10 237:20
excuse 16:16 21:7	45:9 47:24 60:13	239:12,12,14,17	extensive 85:10	254:17 266:3
32:1 50:19 75:14	64:9 277:12	240:11 241:1	295:6	275:3,7 290:11
77:17 144:1	existed 127:13	244:12,18 245:7	extent 89:1 98:10	297:2 299:16,18
203:18 240:18	164:10 189:25	252:10 255:25	102:9 122:9 240:1	302:24 303:1
277:10 300:8	existence 164:14	257:8,13,17	240:5 241:19	facts 82:5 157:7
excused 306:9	191:16	261:11 271:25	external 209:18	195:2 251:10
exhausted 17:3,3	existing 25:9	274:4 290:19	239:8	264:23 265:23
exhaustion 28:21	122:14	291:22 292:8,9,23	extra 79:7	268:1 272:18
exhaustive 13:25	exists 210:23	294:4,8 296:25	extracted 72:5	299:18
exhibit 3:1 8:23 9:2	expand 16:3 281:8	302:5 304:7,14	extraneous 157:17	factual 236:3
9:7,10,15,19,20	281:12	expertise 63:25	extraordinarily	297:14
9:24 12:10,11	expansion 242:23	95:1 105:17	298:19	fail 304:8
13:21,22 29:15,18	expect 48:24 85:12	116:11 120:4	extrapolate 12:19	failed 82:7
34:18 35:19 37:16	expected 15:13	211:15 212:12	extrapolates 18:23	failure 139:23
41:10,12,16 44:19	105:13 123:17	213:4,9,22 223:20	extrapolating	162:2,6,7,14
44:22 45:7,14,20	243:19 244:9	238:10.270:17	133:22 134:2	199:25 200:18
46:21 49:20,21,24	expectedness 172:6	301:19	212:7 223:12	202:5 204:19
51:22 53:13,17,21	expecting 15:12	expertises 86:7	extrapolation	210:15 298:10,13
54:1 55:4 58:5,8	78:25	experts 274:5	18:17	fair 37:8 47:4 67:6
59:16,19,25 66:19	expedited 153:24	expired 121:5	extremely 84:4	67:20 81:17 86:17
67:24 68:4 69:24	280:2	explain 65:23 84:3	111:5 122:23	89:13 96:6,9
70:3 71:14 72:7	experience 57:1	178:4	126:14 132:1	104:3 147:6
72:10,11 77:23	65:11,12 81:14	explaining 88:6	169:13 238:9	150:13,16 156:22
78:12 105:23	89:18 97:22 98:7	explanations 13:7	299:12	169:21 174:3,18
124:13 128:23	101:11 133:20,22	explicit 101:19	eyes 26:13 152:11	176:23,25 180:7
130:8 131:6 138:6	134:2 150:22	142:1	159:1 170:13	187:20 189:5,9
138:12 141:7	164:18 197:24	explored 192:23	e-mail 12:3 20:18	190:13,20 197:17
145:1,19 148:1	212:16 245:4	exposed 122:16	22:20 30:10 44:9	212:13 214:8
151:2 152:9	280:21 292:23	exposure 89:1,5	124:4 127:3	221:9,19 241:9
163:24 165:4	expert 3:3 33:17	120:8 140:4	e-mails 30:7,8	245:5,10 246:15
168:20 171:9	41:20 52:23 55:9	express 25:6 207:2		246:19
172:11 174:3	55:24 56:3,7,10	208:8 249:8,19,23	F	fairness 162:13
176:20,23 183:7	56:23 59:7 65:13	254:1 300:25	face 139:23 256:11	183:25
183:20 187:6,10	70:11 80:16 83:1	304:5	facility 97:6	faith 263:13
191:3 192:24	94:22 97:10,13,17	expressed 22:25	fact 13:22 17:19	Falls 233:9
193:25 201:6	116:8,9 120:7,10	25:3,21 33:21	51:7 52:14 83:23	far 28:5 48:9 80:7
202:25 206:17	120:21 125:16	47:4 85:20 92:8	95:25 122:22	88:19 143:7
209:24 250:2,5,19	137:2 145:19,24	165:5 177:16	123:16 132:2	175:18 182:12
251:1,9,17 254:2	156:22 160:16	219:2 250:1,25	136:13,15 138:15	188:24 189:11,22
264:18 267:23	180:4 213:13	251:17 253:5	141:11 145:21	190:8 203:4 224:5
268:11 280:5	214:24 217:5	265:13 281:21	146:5 154:11,15	263:18
	-			

Videotaped

June 30, 2010

Farley 55:11,17	152:11 154:20	fear 258:23	236:16	33:16 44:25 54:20
57:9	155:16,18 156:5,7	fears 305:16	files 234:12	55:2 56:25 124:5
Farley's 56:16	157:22,25 158:3	February 66:21	filing 218:22 278:6	218:6 240:10
farther 190:9	158:13,20 159:1	67:14 150:12,14	fill 52:6,7 141:7	260:24 289:7
fashion 23:15	159:24 160:8,12	159:24,24 171:24	146:17	302:19
favor 231:8	161:5,10 162:1,10	182:10 185:16	final 7:19,21 34:21	firms 109:18
faxed 57:22 207:9	163:2,8 164:7	189:14 278:19	72:3 73:6 99:11	first 5:22 9:24,25
209:10	165:8,12,22 166:8	279:1,3,4	99:14,17,24 100:6	12:10 15:4 16:20
FDA 10:13 13:22	166:13 167:15,22	fed 89:20	157:24 158:2	17:11 20:10 26:12
16:4,12,18 18:20	170:13 173:6,9	federal 127:21,22	159:1 167:22	32:3 40:15,23
22:3 23:23 24:21	174:22 175:4	207:2 208:8	171:10 181:6	41:24 46:9 48:2
25:14 26:13 34:6	182:8,10,21 183:9	227:16 241:2,17	196:11 198:4,25	54:5 56:2 57:11
42:18,20 48:10	183:15 186:25	253:17 290:24	218:20	59:21 77:5 78:23
52:24 56:5 65:11	197:24,24 198:3	292:8 294:2	finally 242:9	80:16 81:13 82:4
65:15,25 66:1,15	198:10,15,25	295:10	find 33:20 36:13	82:5 107:3,4
66:21 73:7,7,9	200:20,21 201:24	FedEx 30:10 44:17	46:3 69:18 71:1	111:14,22,25
75:23 76:1,2	201:25 211:17	44:17 68:7 209:11	91:24 92:19	122:25 131:6,19
78:13 80:25 81:20	218:9 221:21	feel 135:17 221:24	104:17 124:20	147:7 148:6
81:25 82:9 87:9	233:20 234:17,24	236:2 240:21	126:22 129:8	150:17 154:22
88:22 92:11,21	235:3,18,20 246:6	259:23 260:3	134:22 135:6	156:2 158:12,22
94:16,17,19 95:12	246:7,22,25 254:6	288:19 302:20,22	152:5,12,15,17	164:12,13 169:16
95:19,21 96:2,7	263:7,9,14,25	feeling 294:24	175:2 184:13,13	169:17 171:10
96:19,19,21 97:5	264:1,2,7,10,16	fellow 94:19	184:24,25 192:8	183:8 184:12
97:22,23 98:14	265:1,5,13,21,23	fellowship 42:18	225:12 232:2,4,5	186:13 189:8,9
99:8,12 101:3,11	266:3,16 267:5,8	94:21	232:9,9,16 272:24	196:25 203:12
101:18 102:6,12	267:17 269:20	felt 74:21 220:9	275:18 301:6	210:8,11,22
104:3 105:5,7,11	270:3,21 271:3	260:4 287:3	finding 66:3 103:21	212:10 213:13
105:14,18,19	272:18 275:10	fewer 259:10	119:11 155:9	214:16 225:15
106:5,13 107:13	279:5,22 284:6,21	field 86:9,12 95:13	159:2 232:22	228:9 244:11
107:17 108:6,22	285:23 286:7,15	105:16 106:20	238:4	280:5,7 284:6
109:6 110:15	286:24 287:1,24	107:5,8 108:7	findings 154:15,20	285:13
113:4,9,14 115:10	288:10,14 289:16	109:3 110:23,24	158:20 161:11,20	fish 241:22,23
115:12,20,22	289:20,22 290:12	111:3	162:4 218:12	fit 58:24 59:1
117:19 120:5	290:16,22 291:4,9	fields 111:6 113:7	228:16 231:17	218:10
122:4,8,12,16	291:16,23 292:4	113:12	275:23 280:2	five 68:2 69:10
123:1,12 124:1,12	293:15,24 295:9	fifth 43:3 68:3,12	281:21,22,25	239:3 269:5
124:22 126:12,22	295:21 297:3	68:14,16 69:19	fine 38:8 44:24	276:14 285:2
131:20 133:14,21	301:13 302:21,25	150:2	63:19 112:1,7	fix 214:16
133:23 135:20	303:8 304:10,12	fifth-grade 196:5	152:15 182:4	fixation 136:4
136:11 137:6,11	305:18	200:3	192:5 235:7	fixed 147:13
137:24 139:4	FDA's 131:25	fight 302:21 305:17	finish 43:7 178:11	flagged 19:23,25
140:2 141:9,18	132:18 171:10	figure 282:13	178:12	21:11
143:21 144:5,11	251:10 266:13	file 69:14 158:10,15	finished 69:5 94:21	flash 12:5 20:17
146:10 148:19	267:12,23 268:10	filed 116:24 177:13	197:14 303:23	104:7
149:14 151:7,9	270:11	179:6 181:5	firm 4:17 27:13,14	floor 2:13 254:15
				1 .
L				

Videotaped

June 30, 2010

				rage 322
Flower 2:13	110:10,14 113:3,9	255:14 290:22	16:15,18 32:21	289:9
flows 66:13	110:10;14 113:3,9	299:6	35:22 37:3 38:12	gathering 216:5,25
focus 75:15	116:21 117:2,12	foundation 220:2	38:18 49:18 52:9	297:21
focused 14:8,9	118:20 126:25	221:22	69:12 106:8 148:1	gauge 227:19 241:7
47:11 52:3 187:7	133:17 134:20	foundations 239:13	182:24 206:17	244:4
300:16 302:1	135:24 137:15	four 3:6 30:24	209:7 235:25	general 15:17 16:4
foiled 23:17,19	138:2 139:6,8	55:18 145:4 269:4	244:10 253:25	16:8 29:2 46:24
folks 90:4,5	141:21 157:1	269:13 270:1	269:1 290:23	200:6 233:13
follow 18:8 69:17	165:10,24 166:17	fourth 196:5 200:3	frustrated 48:16	generalities 51:18
76:9 101:13	168:24 170:16	frame 24:17 79:7	fulfilling 193:10	generalization
104:14 105:18	171:13 174:9	216:23 282:8	full 5:12 27:24	262:5 288:6
130:21 190:17	176:12 179:18	293:8	74:22 85:2 163:18	generalizations
263:22,22	180:10 184:2	Frank 1:10 2:21	176:8 236:8,10	262:6
followed 209:11	218:18 220:5	3:6,8,9,11,12,16	264:18 266:22	generalized 271:13
following 11:17	240:8 251:18	3:18 4:7 5:6,14,15	fuller 136:15	generally 7:9 50:4
71:22 144:4 156:4	254:9 266:5	5:17 9:23 11:5,16	fully 221:11	105:25 119:1,2
279:11 282:21	267:14 270:16	16:24 19:8 22:2	function 84:1	293:1 302:9
285:21	278:7	27:22 30:24 31:21	151:21 210:3	generate 217:1
follows 5:7	formally 115:17,18	32:2 38:14 39:6,8	211:23 214:3	274:13
follow-up 32:21	format 30:11 33:6	40:9,23 45:12	functioning 22:19	generated 61:22
46:2 76:6 105:5,7	56:4,17	53:22 64:24 72:6	234:8	63:8 105:16 292:6
105:19 107:14	formatted 56:21	77:20 83:7 85:19	functions 162:25	generation 184:8
109:4 204:9,10	formed 251:22	121:19,21 148:2	further 16:3 84:9	generic 16:5 22:3
207:10 216:11,15	forms 26:19 62:4	166:21 168:20	85:16 102:3	23:22 24:10,22
219:1 280:3	72:21,22 73:2,2	180:7 183:1,6,25	107:22 122:17	36:12 38:7 129:23
follow-ups 17:9	73:23 77:11,16	191:2 204:16	158:20 169:12	130:3 140:7
foolish 181:16	78:9,15 88:21,23	209:24 224:11	177:22 179:1	141:15 148:15
238:22 239:9	101:22,23 103:5	226:14 232:3	190:22 221:2,7,17	149:1 194:23
291:15 295:9	113:13 114:9	245:5 247:15	229:2 242:17	251:11 264:24
foolishness 277:4	146:17	250:18 283:10	263:4,5 265:18	265:15,19,20
footprint 124:3	formulate 135:17	306:6 307:15	289:12 293:9	268:1 287:15
125:12	141:4 179:16	Frank's 3:19 11:20	302:13 303:2,7	generics 23:23
forced 10:20 300:7	formulating 136:8	Fred 2:3 5:2 28:6	furtherance 73:12	129:18
forcing 95:14	137:20	29:16 33:12 185:9	future 16:3 127:14	Geneva 112:5
foregoing 307:6	forth 49:2	201:4 247:3	167:5 173:10	Germany 113:10
foreign 187:7,14	forward 13:7 83:25	free 302:22	245:16 281:1	getting 22:7 57:1
188:7,9,18 189:15	133:25 245:13,17	French 166:18	300:15	186:10 222:4
forgive 180:2	245:22 256:10	frequency 301:10		give 6:19 14:5,9,13
forgot 231:13	257:3,5 259:12	302:6	G	14:13 16:8 21:23
form 61:22 71:11	forwarding 186:24	frequently 212:24	game 283:22 304:7	22:14 23:13 27:23
73:3 74:1 75:18	found 29:6 49:7	frightened 227:11	304:14,16	41:11 44:8 45:6
76:25 77:10,25	82:9 92:11 124:21	258:20,21	gap 26:4	47:2,11 48:24
80:12 83:8 87:17	149:14 163:16	frivolous 33:22	gather 219:8	52:5 54:7 66:17
92:2 93:4 96:10	167:10 227:15	273:19	gathered 69:6 84:5	68:19 83:13 84:8
99:8 100:6 101:7	233:11,14 241:2	front 6:1 9:18	93:16 216:25	85:3 94:15 96:14
	, ,			

Videotaped

June 30, 2010

				rage 323
111:22 122:20	26:3 27:21 29:24	going 6:9 13:8 19:9	125:12,25 126:4,6	handed 46:12
155:25 166:4	34:18 41:16 44:21	19:10,11,12 20:15	126:8 128:20	47:15,16 52:19
190:22 193:2	45:7 49:6 52:2	21:20 23:13 27:25	138:19	handing 53:20
213:18 217:5,9	56:6 61:8 63:21	28:1 34:9 39:18	gotten 197:10	183:1,6
220:16 223:10,21	64:11 67:16 68:15	40:4 43:11 47:10	255:3	handle 179:23
228:1 230:12	69:23 71:23 73:17	48:12 50:12 52:11	governance 158:18	289:5 290:6
231:12 247:3	74:3 75:10,23	56:8 58:4 63:25	211:23	handled 19:4
289:4 297:16	78:17 80:14 83:10	64:13 65:18 71:5	Grand 2:16	handling 81:12
given 18:1,18 21:1	83:13 88:19 93:10	74:5 82:20 83:18	granted 179:9	handwriting 54:25
25:22 30:24 50:13	93:10 96:24	100:9,10,17,18,21	granularity 203:8	55:1,13
74:24 92:9 124:23	100:14 104:16	104:18 105:15,24	great 12:13 180:19	Handwritten 3:6,8
125:1 132:2,11	111:14 115:13	105:24 111:21	256:15 264:1	3:9,12,16,18
136:13 138:1	121:6 125:21	117:4 121:7	greater 179:15	hang 37:14 47:8
140:13 142:14	126:22 133:19	125:17 126:15	292:1	182:20
145:23 158:18	137:4 138:25	127:7 130:13	ground 6:8 12:20	haphazardly 179:7
160:6,10,19 180:2	139:11 143:7,8	138:16 141:22	44:17	happen 173:24
180:4 193:2	146:12 147:25	143:13 144:19	grounds 249:5	179:20
211:16 214:2,13	149:17,21 152:6	145:3,6,16 147:5	group 3:14 112:16	happened 12:21
217:18 218:7	152:11,16,19	153:19 168:1,5,10	206:21 207:19,20	22:11,24 25:24
222:14,19,19,21	153:7 168:4,9	169:11 175:10	298:24 299:18	28:22 29:1,5 34:3
223:16 224:24	175:19 178:10	184:17 186:11	301:16	48:18 51:6 68:9
225:4 227:1	181:21,21 182:13	188:14 215:20	groups 93:24 97:2	82:3,6,12 176:4
228:14,23 229:11	188:25 189:11	220:17 222:9	199:16 207:19	177:24 214:23
235:14 237:9	190:9 192:7	226:3,23 227:16	growing 211:11	249:17 261:24
238:21 239:20	195:12 196:22	228:12,12 231:7	GS-14 94:22	279:2
245:12 246:12,16	202:14 205:20	238:2 240:22	guarantee 72:3	happens 130:17,19
246:21 249:6	208:20,25 210:17	243:4 246:8 247:4	guess 129:10	177:6,7
251:7 255:18	210:22 215:16	250:4 257:14,15	214:22 218:24	happy 199:11
256:6 258:19,19	216:6 221:7	268:15,20 275:21	229:7 259:10	hard 31:8 207:10
262:18 265:24	223:11,13 224:6	277:18 282:2,18	303:19	297:21 301:11
266:9 267:7 270:6	225:12 246:12	285:1,15 292:25	guesstimating	harder 301:1,5
293:8 294:18	248:11 249:20	293:20 296:16	43:24	Hardy 2:16 4:25
299:1 300:20	250:4 254:21	300:24 306:3	guidance 179:2	harm 122:5 132:13
301:16	255:14 256:4	good 5:10,11 28:13	218:7 222:14	132:25 266:2
gives 171:10	257:3,5 269:15	43:24 45:5 49:25	228:23 258:19	270:9
giving 22:11 139:2	271:5 275:19	50:11 53:25 148:4		harmed 284:23
298:22	278:9 279:9,15	152:13 206:15	H	285:25
glad 302:17,18	281:18 283:13	217:5 234:1	half 134:4	harp 73:11
globally 88:16	284:7,9 285:1,9,9	240:19 244:6	halted 129:21	Harvey 2:15 4:25
148:21	285:9,12 292:19	263:9,10 269:22	hand 29:14 36:21	29:16 70:8 247:15
GMP 269:22	292:20 294:7,22	269:23 270:13	44:8 48:2 77:20	hate 19:13 22:1,1
271:25	295:9,21 296:10	284:18,18 294:24	77:23 81:9 124:11	245:11 291:21
go 6:7 12:15 13:6	299:7 303:11,22	Goodwin 145:16,18	163:23 201:2	hauling 31:18
14:4 15:23 17:8	305:25	Google 124:1,9,20	251:15 275:22	Hazard 26:23
19:10,20 24:17	goes 113:10	124:24,25 125:4	280:4,6 290:14	60:22 63:7 64:4
				<u> </u>

Videotaped

June 30, 2010

70:23 71:5 73:6	197:15 213:11	295:17	H 97:3	implosions 28:19
74:18 75:7,18	heard 42:25 115:16	Honestly 215:1	III 2:3	imply 259:17
76:24 77:9,13,18	128:19 143:18	honored 289:13	imagine 42:18	implying 271:23
77:24 88:7,11	235:22,22	hope 28:2,3 94:14	immediately 11:16	importance 114:18
91:8 92:13,15,23	hearing 46:24	128:12 138:9	156:4 158:22	important 6:10
98:9,12 119:11	hearsay 274:16	174:14 198:19	169:9 291:12	110:21 111:5
195:24 196:11	heart 298:3	248:2 258:16,17	impact 70:14 82:13	125:24 128:5
200:14 202:23	heavily 246:22	262:5 302:19,24	102:4 117:15,23	138:22 141:13
1 7 7	284:12	Horan 106:10	127:6 139:25	151:23 168:25
203:20,21 204:6 206:5 207:8 208:4	heavy 35:10 260:2	hospital 274:21	142:1 144:12	169:7,13,14
	296:24	hotel 33:3	156:10,16 157:19	171:23 173:16
208:7,15,16,24		hour 78:20 168:6	165:7 169:9 170:8	174:11 185:3
209:3,9,17 215:7	hedge 174:15	hours 15:8 78:24	176:22 186:3	191:14 232:8
234:15,19 235:4	heeding 62:19	79:7	201:25 233:15,17	238:9 255:1 265:4
235:15,16 288:11	held 4:10 33:21	huge 160:20 215:3	241:21 262:4	impossible 299:21
head 6:16 260:10	help 141:7 292:14	nuge 160:20 213:3 248:7 254:22	273:9 288:5	impression 146:20
heading 253:18	helping 53:1	hundred 8:19	impacted 83:16	229:13,15,18
headquarters	herring 117:1,11	114:7 250:14	130:4 141:14	230:2
210:3 211:3,5,9	118:19,22,25		157:8 249:10	improved 233:21
211:16,22 212:18	high 241:19 255:8	286:14	288:7	Improvement
212:20,24 214:3,4	260:8 286:23	hunt 185:4	impacting 219:12	26:24
214:10 223:6,14	297:7 299:19	Huntington 2:9		improving 27:16
263:20	300:24	hurt 305:9	impacts 224:10	inability 237:3
health 26:23 49:3	higher 112:21	hypertension 96:25	impartial 80:11	inaccuracies 49:8
56:6 60:22 63:7	298:3	97:1	83:4	101:21
64:4 70:23 71:5,7	high-frequency	hypertensive 97:4	impermissible 13:5	inadequacies
72:24 73:4,6,6	286:10	T	implement 98:8	169:23
74:18 75:7,18	high-level 250:15	Iceland 210:4	154:18 167:11	inadequacy 161:12
76:24 77:9,13,18	high-profile 300:4	213:25 214:10	214:7	inadequate 85:21
77:24 88:6,11	300:6,12	ICH 73:2	implementation	139:6 140:17
91:7 92:13,15,23	high-volume	idea 45:5 69:10	155:15 157:21	153:23 173:2,13
98:9,11 117:20	107:19	120:13 127:6	158:4,19,20 167:7	176:10,22 179:12
119:10 122:11	hired 81:3 83:14	136:24 147:13	169:25 173:14	170.10,22 179.12
190:2 195:23	179:21 222:14	286:13 287:20	187:3 192:2 212:2	217:12,13 221:22
196:11 200:13,22	288:23 303:12	identification	228:17 280:1	228:17 255:4
202:23 203:20,21	historical 152:13	45:10 47:25 53:18	281:4,5,8,24	256:16 269:21
204:6 206:5 207:7	history 98:4 149:8	55:5 58:9 59:17	284:17,18,19	280:3 284:3 292:6
208:4,7,15,16,24	159:6,10 161:4	60:14 69:25	302:10	
209:3,9,16 210:13	hit 294:2,4 296:25	identified 211:17	implemented	inadequately 82:8
210:15,22 215:7	297:1	identifies 210:16	161:17	inadvertently
234:14,19 235:4	hold 47:21 133:23		implications 16:5	276:20
235:14,16 286:8	134:1 238:7,10	identify 64:25 81:25 82:1 150:18	182:8 257:6,10	inappropriate
288:11 293:25	holding 68:4 211:5	163:8 195:10	304:24	145:8,14 171:1,22
297:4	211:6	1	implied 63:13	incident 91:10
hear 28:1 72:25	holds 97:24	210:21 IDD 66:10	implies 154:12	107:23 150:6
79:13 111:2	honest 239:16	IDR 66:19	172:13 173:5	incinerated 103:7
	l	1	1	

Videotaped

June 30, 2010

1	· ·		I	I
Index 2:20 3:1,11	83:22,23,24 84:5	231:16,18,24	inquired 92:8	187:17 188:1,23
267:22	80:8,21 81:16,18	230:20 231:1,15	inquire 105:6	184:5,7 185:23
222:16 238:8,14	74:19 78:11 79:25	229:16 230:3,7,17	innovator 95:14	182:22 183:21
138:8,10 220:11	73:5 74:9,11,15	227:20 228:13	innovative 95:10	173:23 176:5
119:22 123:8	70:17 71:25,25	225:13,18,22,24	ink 54:25	172:7 173:10,11
independently	66:17 67:23 68:10	222:15 224:14	injury 139:7	169:7 171:7,19
250:13	58:23 62:7,9 66:4	221:14,17,18	127:18	161:19 167:6,20
166:3 211:6	44:10 51:3 53:1	220:16,22 221:3	injuries 121:23	158:1,20 159:2
125:8 127:9 155:8	27:14,20 41:24	219:9,11 220:16	injured 128:1	156:11,24 157:8
123:22 124:6	18:10,19 25:14	217:1,23 218:17	injunction 60:7	155:1,13 156:4,8
109:24 114:21	11:18 17:20 18:1	216:5,5,10,13,24	111:25	154:12,12,15,20
independent 74:22	information 7:11	210:5 214:2,9,13	initials 111:20,22	153:22,22 154:9
IND 95:6	influx 262:17	207:7,12,18 208:6	214:4	152:4,8,22,24
incumbent 225:12	influenced 273:13	204:25 205:23	78:23 175:21	150:22 151:3,7,24
301:15	infectives 94:23	193:16 199:16	initially 45:18 60:8	149:13 150:12,18
increasingly	infected 270:4	190:12,24 193:9	261:1	120:11 142:25
242:8 301:9	305:8	186:19 188:15,16	214:16 218:25	108:3 109:4
increasing 134:5	294:8 296:15,24	182:14 185:13	191:19 195:23	106:2,3,11 107:14
increase 273:12	inexperience 241:7	179:15 180:8	99:9 158:10 176:3	102:23 103:20
239:9	ineffective 158:18	177:22 179:4,13	initial 80:24 95:17	97:6 99:10 101:20
incorrect 237:23	275:11	177:2,4,8,18,21	inhibit 303:7	81:24 82:9 93:9
174:15	98:6 123:10	173:2 176:8,22	inherent 300:20	73:7,8 81:24,24
incorporated	60:21 65:11 98:5	168:22 169:1,8,12	Ingrid 112:11	48:10 66:11 68:9
incorporate 221:13	industry 23:23	165:6 167:4	118:6 262:25	13:2 27:7,8,10,11
81:15 101:21	induced 273:11	157:18 163:17	ingested 103:24	inspection 7:20,22
incompleteness	INDs 96:8	154:14 155:10	ingest 128:4	inspecting 106:13
101:24 177:20	243:14	152:1,3 153:23	224:15	151:16
incomplete 101:23	180:21,22 211:24	150:3,4,6,11,14	196:4 200:7	inspected 151:15
inclusion 223:17	112:25 113:2	147:19 149:8	181:4 182:11	246:24
38:20 143:5	49:13 100:22	142:3,19 146:15	117:3 177:18	190:22 214:18,23
including 35:4	33:18 34:13,13	140:23 141:8,13	115:21,24 116:1,3	175:20,23 180:16
286:17 288:1	individual 26:19	138:11,23 139:1	informed 69:21	insight 151:25
109:5 276:9	indications 56:20	135:25 137:7,19	176:11	275:6
includes 18:22	228:14	134:12 135:19,21	information.Do	109:16,17,18
249:16	225:4 226:25	126:23 128:13	297:20 301:19	65:18 82:12
163:22 224:8	223:16 224:24	123:17,20 125:17	290:12,16 291:20	41:9 53:1 61:1
72:10 74:23 79:21	101:17 164:10	119:4,16,21 121:1	289:2,12,23	inside 26:11 28:20
included 9:19,20	indication 56:22	117:21,25 118:14	271:18 278:2	305:8
281:12	39:7 269:7	113:24 114:5	270:24 271:9,14	insecurity 304:6
174:11 182:14	indicating 32:7	104:1 110:3,18	267:20,23 270:22	insecurities 248:14
127:22 140:24	indicates 228:16	94:10 95:18 103:6	266:7,24 267:19	insecure 228:20
include 119:8	280:8	93:20,23 94:1,3,7	261:24 262:3	132:4 297:5
147:17 271:1	147:21 150:25	90:6 92:17 93:16	245:8 255:15	inquiry 62:2 89:17
146:14,23 147:11	indicated 145:23	85:22 86:14 87:22	234:18 237:9	inquiries 145:7
	indicate 88:14	84:20 85:3,5,9,21	232:1,10,18,19	156:9

Videotaped

June 30, 2010

				raye 320
100.10 101.5 10	101.20 102.12	investigating	109:3 124:15	174:19 182:9
189:18 191:5,19 191:23 192:13	101:20 102:13 256:7 264:2	investigating 233:25	143:21 144:6,14	185:16 189:14
'	296:13	investigation 61:4	143.21 144.0,14	191:2,11 193:3,13
193:8,9 195:7 211:18 214:5,16	intensive 150:12	61:9,12 62:14	191:3 198:1	191.2,11 193.3,13
1	intent 71:21	63:6 64:1 85:17	201:20 207:7	216:23
216:8,9 218:9,12	•	88:9 91:7,9 119:7	201:20 207:7	jeopardize 224:25
228:16 231:16,20	interact 213:25	123:25 142:19	287:20	258:13 305:5
232:22 233:9,12	interaction 59:9	276:11	issues 9:13 15:18	jeopardy 296:14
233:16,22 246:25	interactions 59:6 242:18		15:20 17:12,17	Jersey 107:6
248:23,25 249:1		investigations 25:16 51:4 143:19	19:15,23 21:1,3	150:19 151:5
264:8 269:19	intercurrent		21:10,11,22 22:22	150:19 151:5
270:17 275:23	163:20 298:12	investigator 93:1,7 93:9 142:25	22:22 23:6 25:4,7	182:15 233:9
276:5,15 279:3,22	interest 237:25		25:12 49:4 63:24	253:21 280:20
280:2 281:1,22,23	238:2	Investigators 106:10	83:15 85:15 96:8	Jim 55:17 56:16
281:25 284:5,12	interested 19:22		97:18 100:10,13	job 94:16 224:13
288:1,2	21:7,9 31:17,18	involved 28:18		256:16 293:17
inspectional 184:2	32:19 151:12	34:12 98:3 115:18 212:18 214:5	100:14 102:4,7 118:16 122:24	Johnson 45:22
inspections 10:13	229:10	l	124:23 125:1,14	46:23 116:14
26:10 34:6 65:25	interim 163:8	222:4,9 276:8 involvement 98:11	124.23 123.1,14	join 270:19
81:18,19,22 82:5	231:18 246:23	124:4 242:8	135:22,23 136:9	johe 28:15
85:14 92:11 160:8	intermittent 15:9		135.22,23 130.9	judge 145:16,18
163:16,17 187:19	51:7	involving 297:22	150.11,25 159.10	220:11 222:16
246:7,13 247:1	internal 16:13	300:11		238:8,14 242:21
264:15 284:6	26:21 74:25 85:14	in-house 61:5	157:20 159:23,25	242:22 253:17,18
inspector 162:10	109:16 203:17	irrelevant 11:14	160:6,14 161:15	ł
234:24 235:19,20	204:3,13 205:20	127:5 128:15	162:19 163:4	253:20,21,22 254:23 292:8
inspectors 12:25	206:1 209:5	isolated 107:23	165:3 171:18	judges 127:23
26:13 29:6 75:23	internally 175:25	issue 18:9,12,14	172:6 174:6 189:25 191:9	238:3 241:2 254:1
80:25 99:9 106:13	international 211:4	19:24 21:2 87:11		290:24 294:2
152:12 159:3	Internet 124:3	87:12,13 99:23	199:23 205:8 209:19 211:17	judgment 114:11
198:3 264:10,16	126:7,12 299:7	108:13 111:16		132:11 243:17
288:10	interpret 191:15	112:18 115:3	212:9 213:1 214:11 216:15	265:24 270:6,12
inspector's 78:13	interpretation	116:25 117:5,6,17		July 62:17 124:15
102:6 235:3	169:24 171:22	117:23 119:24	248:8 249:10	134:17 153:18
instruct 126:21	172:1	120:2 121:2 122:5	263:16 267:2	161:11 187:3
instructed 79:4,10	interrupt 9:14 19:7	133:23 134:1	277:5 289:8 300:1	B
79:12 122:20	22:2 33:8 89:25	138:19 155:2	item 11:17,17 29:25	188:10 212:1
125:11,21	96:4 140:10 170:1	172:16 189:1,2,11	30:2 269:12,16,16	276:12
instructions 21:8	284:25 292:19	196:3 210:10,16	items 3:4,5 30:12	jump 260:7
insufficiency	interrupted 15:9	210:21,23 211:14	41:21 42:9 43:11	June 1:14 4:13
199:24 200:10,17	intimate 146:3	212:12,13 214:25	53:22 67:22 269:5	43:25 50:6 62:8
204:22 207:20	intimating 145:20	224:22 237:9	iterations 34:20	92:8 135:10 147:2
208:2	introduce 4:19	244:4 254:22	T T	154:4 177:7 218:3
insufficient 214:8	introduction 152:8	257:25 263:18	January 164:7	225:8 242:15
integration 212:17	investigate 263:5	274:25 291:2	166:12 170:14	243:1,2 247:25
integrity 101:5,12	investigated 263:4	issued 106:10 107:5	100.12 1/0.14	250:18 266:21
				I
Proceedings of the Control of the Co		······································		

				Page 32
272:7 283:9 306:7	138:11 191:21	214:15 219:21	96:8	learn 116:19
jury 6:1 241:12	220:10 231:10	220:13 223:10	labelings 96:1	237:21
242:11 244:10	287:10,12 295:20	224:5,14 225:10	lack 80:20 84:20	learned 240:1
justify 97:2	kinds 48:14	225:10 227:19	92:13,23 132:12	251:8 259:25
justify 97.2	knew 111:20	229:19,24 234:10	139:12,20 140:2	learning 225:2
K	127:12 207:13	235:6 236:1,5,13	141:14 153:9	leave 125:12 153:7
Kansas 2:17	217:19	238:6 241:22	175:5 200:14,17	223:22 296:1
Kaplan 2:15,22,23	know 7:1 9:9 13:15	242:12,16,22	208:3 231:10	leaving 259:19
2:24 4:25,25 7:21	13:16 18:23 19:6	244:4,17 252:6	234:19,21 237:9	263:20
20:8 27:1 41:3	19:22 20:18,18	254:23 255:6,19	266:1 270:8,17	led 91:7 158:20,23
70:5 72:25 79:12	21:12,19 25:16	256:3 260:1	273:1 288:13	226:22 227:4
79:16 84:12,15	30:17 33:24 39:4	261:14,15 262:1	laid 12:24 163:15	230:7,20 231:10
94:8 112:8,10,13	39:5 43:21 44:25	262:17 267:9	language 218:5	238:20,23 240:24
145:6,12 247:14	48:21 50:23 54:18	271:8,25 272:5,21	lapse 138:9	241:14 251:24
247:15 252:8	56:12 61:9 65:5	272:22 273:22	lapses 130:15	252:2 255:10
254:12 255:16	69:10 75:10 82:3	276:16,19 283:15	laptop 22:18	256:8 277:24
258:2 262:14	84:2 90:22 91:3,6	286:6,19 287:10	large 66:2	289:19 304:8
266:12 267:16	91:17,18 98:4,20	287:14,17,25	largely 16:12	left 28:5 76:13
268:14,18 270:15	99:15 103:16	288:16 291:19	larger 40:25,25	124:3,5,9 133:5
270:19 274:15	105:10 112:13	295:13,23,23,25	45:13 196:22	136:18 158:24
282:2,11 283:6,9	116:23 119:5	296:9 297:7	301:7	189:6 210:2 213:7
283:17 284:20	123:9 125:13	298:24 299:24	late 15:14,15	230:21 285:4
285:5,11 286:22	127:19 129:24	300:5,9,12,24	188:15 276:22	287:21
290:1,4,8 291:13	133:15 134:21,25	302:4,9 304:15	277:6	legal 83:19 98:17
292:10,18 294:20	135:8 136:10,18	305:18	law 1:11 44:25	99:16 125:18
296:7 297:9	138:21 139:21,25	knowing 221:2	141:12 166:7	148:18 219:16
302:15 303:24	141:23 143:19	229:2 239:10,11	251:15 253:25	legitimate 179:5
305:24	144:20 147:18	239:12 241:7	256:5 259:21	224:13 249:5
Kaplan's 20:14	152:23 153:1	knowledge 69:11	260:24	Leikin 26:22 70:23
Karen 1:10 2:21	155:12,14,15,18	100:2 102:17,20	lawyer 28:15 53:7	75:18 77:12 137:1
3:11,12 4:7 5:6,14	155:21,23 156:2	129:17 134:25	lawyers 17:12 36:5	235:15
31:21 53:22	157:24 158:17,25	156:13,14 202:25	38:2 62:6,11 63:2	Leikin's 73:6 74:18
250:18 283:10	159:19 161:23	205:21 238:21	105:7 116:15	75:7 206:21
295:19 306:6	163:13 165:13	273:14 289:17	126:21 137:23	lengthy 11:7,17
307:15	168:4 173:8,25	known 50:12 84:20	212:11 226:19	278:13
keep 48:7 69:5	175:21 184:6,12	117:10 224:20	229:1 236:3	letter 36:8,12 49:7
168:1 199:10	185:1 186:1,6,7	293:5	267:21 268:3	66:21 70:23,24
218:11 259:6	186:14 187:5,7,13		lax 95:11 138:9	71:7 99:2,13
277:3	188:6,8,13,19	L	lay 26:7	134:1 159:9
kept 123:2	189:15,16,17,22	L 2:15	lead 157:23 177:22	161:10 163:1,5
key 8:20 9:10 68:8	191:9 193:18,20	label 67:4 95:11,15	225:24 290:24	164:6,10 165:14
89:6 128:3 170:4	194:10,17,20	95:17 126:19	298:15	166:16 169:23
kicks 130:20	200:5 202:16	127:8 299:7	leading 88:15	170:2 171:21
kind 48:13 55:21	204:4 209:1	labeled 152:22	251:21 252:3	172:24 174:20,22
106:1 108:10	213:17,24 214:14	labeling 95:9 96:2	256:15 298:18	183:8 195:24
	·			

Videotaped

June 30, 2010

				Page 328
203:23 204:3,5,6	leverage 65:11	75:8	152:16 168:7	loose 30:25 47:16
203.23 204.3,5,0	liability 1:5 4:8	listen 73:18 191:7,7	185:8 206:12	60:5
204.10,12,21 205:25 206:10,20	127:19 243:24	251:6 297:15	243:4	Los 2:13
207:1,13,18,21	lieu 113:14,15,16	listening 247:17	longer 10:17 180:8	loss 255:6
208:6,23 209:20	148:19	listing 20:25 31:14	221:10	lost 37:7
216:19 259:16	life 53:25 164:13	36:9,11 46:6,13	look 11:1 17:22	lot 17:25 19:18
278:18,25 279:5	lifetime 111:24	51:15	20:9,11 23:16,18	22:24 23:8 25:11
280:13	lifted 82:4 149:16	lists 47:7 81:9	24:1 46:3 53:8	25:16 29:4 33:20
]	151:19,20	literature 88:19	54:8 62:4 69:19	48:20 49:14 52:20
letters 36:2,5,6 38:7,7 48:10 49:2	light 110:19 141:11	96:18	71:3 72:18 78:4	120:6 130:19
66:15 71:2,11	172:11 200:20,21	litigation 1:5 4:8	83:15 88:18 89:7	160:7 167:19
73:9 133:24 158:8	279:16,21,22	30:4 56:2 57:4	89:15 106:6	175:23 179:2
159:7,18,20 161:4	292:8	116:16 121:22	123:24 136:21	214:18 219:8
163:10 165:2	lightly 287:2	122:1 127:17	138:8 139:1	225:9,22 226:15
167:20 171:3,11	lightweight 35:9	128:5 217:6 222:5	140:21 142:22	228:2 232:6
172:8 193:11	238:7 296:17	226:15 237:17	150:17 160:21	236:17 239:10
198:5,7 202:13,20	liked 7:15 51:8	240:23 241:4,16	171:24 174:6	246:24 248:17
246:8,8	108:11 120:23	244:1 245:17	181:15 195:19	257:11 270:25
let's 10:24 14:7,12	169:1 223:7,15	252:10 253:18,19	207:22 229:4	288:8 297:7
20:23 24:17 29:24	293:5	253:20,21,22	232:6 234:11	lots 85:8 131:22
34:18 37:21,21	likelihood 118:4	255:20,22 257:13	250:8 268:24	136:18 270:4
46:9 64:7,11	139:7 159:16	258:14 263:16	272:10 275:13	271:20,22 272:1
76:21 78:17	243:8,22 300:24	293:3 295:20	295:3 299:22	loud 6:15 279:20
111:14 121:6	limited 70:20	296:14 299:25	looked 23:5 24:9	low 141:15 301:4
137:4 145:18	241:15 244:12	303:16	36:12 67:17 82:19	301:10,14 302:6
146:12 147:25	260:6	little 6:5,23 43:3	134:7 137:6	lower 300:25 301:5
148:4 153:7 159:5	limiting 29:10	56:1 64:10 81:6	208:22 234:24	lunch 7:14 43:17
168:6,9 178:10	line 17:19 18:3,14	81:10 123:14	235:17 237:14	138:19 242:13,15
181:21 182:24	22:21 161:18	138:13 140:4	248:1 267:5	300:1
183:20 184:24	241:14 244:18	150:3 172:25	271:20,22 273:16	luncheon 121:11
195:12,13 210:11	251:21 252:9	186:19 227:15	282:14,15 287:6	
212:10 215:18	267:12 269:12	228:19 233:9	291:9 297:3 299:6	M
223:22 226:2	271:16	238:2 263:23	looking 7:10 63:6	magnitude 119:25
269:15 278:9	linear 290:18	285:1	66:11 81:1 82:2	243:24 244:15
279:9 292:15	lines 152:25	liver 210:15	86:14 87:5,19,20	292:24 293:3
303:22 305:25	link 208:11	lives 111:20	88:2,3 90:2 91:23	Mahoney 1:12 4:11
level 94:22 112:21	list 7:14 20:6 22:5	LLC 2:3 3:14	108:17 114:15	main 292:21
157:25 196:5	22:11 25:23 44:8	187:12	120:3,3 123:6,9	maintain 111:6
197:19 200:4	44:12,13 46:1	LLP 2:8,12,16	125:17 135:20	126:15 174:7
211:5,10 238:10	47:2 48:24 49:8	loathed 56:1	138:17 146:5	maintained 117:24
241:6 274:9	51:20,20 52:5,9	lobby 15:11	160:9 172:24	125:20
leveling 95:13	52:12,18,19 53:7	local 210:4 211:7	216:12 301:25	maintaining
levels 139:22,22	62:24 73:16 74:7	211:10,12 214:11	looks 18:20 47:17	287:24
242:8 273:21	76:1,7 78:7 299:1	long 8:23 10:11	184:4 295:8	making 34:9 39:8
298:4 299:10,20	listed 3:4,5 53:22	15:7 74:6 140:3	loop 104:6	75:12 125:22
	· /		-	,
		AAV.	A A A A A A A A A A A A A A A A A A A	

Videotaped

June 30, 2010

			· · · · · · · · · · · · · · · · · · ·	
133:15 134:3	mark 41:9,15 43:11	MDL 1:6	50:6 51:18 65:8	156:24 157:22
141:10 145:7	44:22 45:7 47:22	mean 17:13 101:24	65:21 66:7,9 92:8	158:1,5 160:7
173:1 175:18	64:25 112:12	110:4 120:2,3	162:11 175:10	187:4 212:2 214:7
190:6 219:7 224:7	marked 3:2 8:7,23	125:6 150:24	177:7 185:12,20	284:5
242:17 248:3	9:7,9,16 12:10	172:23 199:22	185:21 188:23	microphone 77:21
288:6 291:3	29:15 31:19 45:3	228:12 243:15	199:4,5	183:3
malfunctioning	45:9,14 47:25	303:25	meets 115:15	middle 278:12
61:14	48:3 49:21 53:17	means 109:11	Megan 7:13 14:21	mid-afternoon
malign 295:4	53:20 55:4 58:8	189:22 261:15	44:1 56:12 177:7	250:8
management	59:16 60:13 69:24	281:3 287:21	memory 8:10,21	Miller 7:13 9:12
184:20	70:3 77:23 105:1	288:14	195:11 206:15	10:4 12:2 14:22
managers 211:13	124:12 151:2	meant 17:14 24:5,5	mention 22:3	15:12 25:25 43:17
mandatory 274:9	163:23 183:7	78:10 220:3	mentioned 22:10	44:1 45:21 46:23
275:8	201:2	medical 23:5,7	24:21 89:11 91:11	50:6 51:17 52:6
manifestation	market 1:12 4:12	52:25 65:15 88:18	103:19 105:21	53:7 54:20 56:11
235:9	61:3 85:7 88:16	96:7 100:22	109:23 111:18	65:8,21 66:7,9
manner 277:25	88:25 89:2,5	114:11 118:10	144:23 174:20	68:7 84:8,12,13
manufacture 89:8	102:19,23 103:24	120:5 136:6,10	182:1 202:4 206:5	84:15 116:14
116:11 272:12	115:6,14,23 116:5	221:20 254:4	242:25	124:5 154:3
manufactured	132:12 140:3	297:14 298:10,14	mentors 25:14	160:23 223:5
128:4 140:13,21	147:8 197:3	301:25	menu 113:8	241:3 242:14
260:23 262:9,25	210:24 265:25	medications 216:14	merged 71:13	278:7 289:7
manufacturer	270:8 271:21	MedWatch 26:19	183:19	302:19
140:13,22 148:15	272:13,23 286:11	70:18 72:21 73:2	merger 154:19	Miller's 223:21
149:1	286:13 287:12	73:14,14,23 75:3	212:17 214:20	224:9
manufacturing	300:20	75:20 76:11,14	Merit 1:15	million 120:12
61:2 63:24 86:21	marketed 156:10	77:8,11,16 78:9	message 197:10	millions 261:5
86:25 87:21,23	156:15	78:15 87:22 88:21	met 5:17 7:13 14:17	276:21 304:18,18
88:3,14,25 89:15	marketing 95:14	90:19,23 101:22	15:4 43:25 44:3	304:18
90:24 91:5,19	markets 103:10	101:23 110:2,3,8	184:20	mind 11:20 52:7
92:5 93:19 97:6	markings 41:7	110:10,15,17	method 269:20	147:14 174:4
97:11,14,18 120:3	marks 30:23	111:14 113:1,2,16	301:6	189:7,23 190:6,12
129:13 130:3	material 7:9 27:25	113:23,25 174:19	methodologies	208:12 248:9
131:13,20 140:12	39:19 48:14 169:8	191:4,12 192:11	302:4	mine 88:20 126:1
140:20 162:19	177:8 178:8	193:3,14 195:5	methodology	143:12 199:8
219:11 248:8	materials 36:10	216:6 217:1	299:22 300:18	271:5 290:13
265:15 269:23,23	matter 44:3 78:19	297:21	301:23 302:2	mined 88:13
270:2,13	78:22 79:19	MedWatches 74:9	meticulously 19:9	134:11 142:21
map 78:8,14 82:3	138:15 179:11	76:23 103:5	Metrix 160:11	mining 122:9,24
87:13 110:13,14	219:25	112:17 274:22	me-too 95:12	143:11 271:2
mapping 113:13	ma'am 20:5 23:21	meet 14:19 15:12	MHRA 26:10	Minnesota 146:18
March 59:3 154:19	36:24	83:20	81:18,22,25 85:14	minus 114:12
158:5,22 187:4	McCaffrey 106:10	meeting 13:17,17	153:21 154:8,11	minute 39:4 75:2
188:12 212:3	McCAMBRIDGE	14:5 20:4 21:11	154:15,18,23	104:17 106:24
margin 17:24 299:3	1:11 4:11	43:17 44:15 45:21	155:1,4 156:8,11	178:11 186:12
			1.	
		343		

Videotaped

June 30, 2010

				Page 330
20102172	N. 0.10.4.00	207.15	26.10.64.9	85:19 122:7,21
	Monee 2:12 4:23	307:15	36:19 64:8	123:1 128:23
1	money 121:23	N	negate 178:9	130:9,10
80:2 144:22	226:15 239:10	NAI 150:23 151:24	288:18 289:24 303:2	N.J 1:16
146:13 175:9	243:17	153:12 169:6	'	nodding 6:16
1 /	months 125:4	171:20	negative 153:15 negligible 303:3	noncompliance
225:18 230:6,14	158:7,23 276:15	naive 220:6 228:19	negotiate 190:2	18:20 154:21
1	Moriarty 268:16	254:23 258:23	negotiations	158:24 211:17
300:21	268:18	261:10	161:24 200:20	nonreporting
	morning 5:10,11	naivete 63:23 180:3	nervous 21:17,20	178:6
39:12	13:18 14:12 23:1	225:3 277:4,5	never 53:6 64:2	nonsubmission
mischaracterizes	24:2,3,4 25:3,5	name 4:21 5:12,17	99:17 102:12	218:13
170:17	26:7 103:19	149:1 307:19		non-Digitek 18:22
misgivings 245:6,8	167:13 170:3	Naranjo 111:11	109:22,24 122:15	normal 115:5
1	motive 242:22	114:13	138:25 146:6,7,9	139:21 298:4,4,15
1 ' 1	Motley 2:3 5:2	narrative 75:11	153:25 163:5	
240:5,21	124:5 278:7 289:7	76:6,11 110:19	164:3 202:24	299:9,9,20
misplaced 277:13	302:20	114:12 284:8	212:17 215:8	notable 210:1
	Mount 2:4	narratives 101:22	222:3 225:4	Notary 1:17
	move 32:17 56:1		230:23 231:6,9	notated 50:13
37:20 51:15 141:8	90:1 145:9 169:4	143:14,15	239:16 241:13	note 41:18 43:23
159:16,18,20	211:20 214:16	national 109:20	250:13 262:3,8,22	158:9,15 299:3
165:6 190:12,24	245:16 259:12	nature 119:2,3	267:7,20 268:3	notebook 39:18,22
1	moved 42:13 94:24	241:20	271:22	40:12 41:1,2,7,20
Missouri 2:17	151:13,17 245:22	NDA 95:8	new 86:15 87:6	42:2,5 44:15
misstates 139:9	movement 211:11	NDAs 96:8	107:5 123:17,20	45:13,20 46:14,21
mistake 176:14	moving 245:13	necessarily 73:24	150:19 151:5	59:24 60:3 69:19
mistaken 154:10	multifunctional	259:22	152:22 164:17	notebooks 30:25
mister 84:14	215:13	necessary 230:14	174:11 180:12	31:5,24 32:1 39:9
misunderstanding	multinationals	need 6:25 12:5	182:15 210:14	40:8,17 54:2 60:5
237:1	212:25	19:20 20:2,16	211:19 221:13	67:17
mixed 42:19	multiple 21:5 61:13	33:5 42:20 43:18	233:9 237:20	noted 107:17
modelers 27:15	139:17 151:17	54:8 57:24 58:7	253:21 278:4,8	156:23
modified 148:22	165:5 266:10	84:8,8 96:15	280:20 288:22	notes 3:6,8,9,12,16
	Multi-District	109:8 111:3	289:2 292:25	3:18 17:23 20:2,4
283:8 294:9	253:18 255:20	119:20 126:18	295:2 296:12	36:21,22 37:1,6,9
	Mylan 5:1 70:25	127:13 142:4,16	304:7	48:6,8 49:12,14
173:18 177:9,23	195:25 202:24	174:5 180:24	news 203:18	50:2,5 51:17 55:8
177:25 196:7	203:17	181:17 194:20	nice 36:18	65:4,6,6,20 66:5
	myth 265:13,16,18	207:22 227:12	Nigel 55:16 59:8,13	71:24 81:8 135:7
278:4 288:21	265:21	232:16 285:13	245:18	notice 1:17 29:18
297:8	myths 251:11	294:6,9 301:7,20	night 13:17 14:6	33:4 35:19 67:24
modus 65:15	264:24 268:1	needed 61:7 83:18	16:2 19:23 20:7	106:11 122:25
molecules 94:23	272:18	95:1 117:25 152:1	22:11,24 23:17	novel 140:4
1	M.D 1:11 2:21 4:7	160:13 220:17	25:5 29:23 33:4	November 241:4
174:2 192:17,25		needs 28:22 33:10		243:21,21
	5:6 250:18 306:6	neeus 20.22 33.10	/4:11 84:/,23	243.21,21
17 1.2 172.17,25	5:6 250:18 306:6	needs 20.22 33.10	74:11 84:7,23	243.21,21

Videotaped

June 30, 2010

<u> </u>				1 dgc 331
number 13:22 23:3	observation 92:21	October 153:23	100:21 101:2	once 13:24 200:11
29:25 30:2,13	102:6 105:4,8,20	165:17 166:2	104:14 106:18	215:14 225:4
35:19 37:24 38:9	108:8 153:22	233:10 243:11	107:2 108:10	ones 91:14 172:20
38:14 41:12 43:11	156:24 158:13	290:23 291:6	109:12 113:5	192:14
46:21 48:3 51:22	182:8 190:19	294:2	115:4,9 121:4	one's 293:2
51:25 59:25 65:2	234:6,17 302:21	offer 100:18	122:3 128:3,7,11	ongoing 92:23
76:8 112:16	observations 12:25	offered 295:1	128:15 131:9,17	181:4 234:19
114:14 121:22	26:14 72:9 81:1	offering 100:22	134:16 135:4	open 133:6 259:19
132:11 173:19	99:9 101:21	261:11	141:6 142:18	291:3
194:20 204:15	123:13 142:25	office 42:14 97:8	144:21 147:25	operandi 65:15
215:3 237:18	171:11 173:13	107:6,9 167:9	149:19 152:18	operate 148:21
259:3 265:24	178:5,14 180:17	215:17	153:3,5,16 157:17	211:7
269:13,16,16,25	180:21,22 184:2	officer 52:25 65:16	161:3 164:1	operating 151:5
270:7 275:14	187:6 191:5,19,23	136:10	167:25 173:6	208:13
298:14	192:13 193:7	offices 1:11 4:11	178:3 181:22	operative 276:8
250.14	205:7 216:8	official 81:8 110:1	182:3,20 187:22	Operator 2:19 4:4
0	218:10 223:1	135:3	189:20 191:2	5:4 64:13.19
oath 121:18 254:1	232:19,24 246:22	off-label 96:22	194:15 195:15	77:21 104:18,22
304:3	249:21 250:11	oh 24:5 49:7 128:25	196:25 197:5,12	121:7,13 168:10
object 74:1 80:12	279:23 281:10	163:15 183:16	198:18 201:3,9	168:15 183:3
83:8 93:4 96:10	283:25 284:13	243:23 260:22,22	202:22 203:7,24	215:20,25 226:3,9
101:7 116:21	observer 83:4	304:15	208:10 209:12	247:4,8 285:4,15
117:2,12 118:20	observing 99:22	Ohio 2:10 4:18	210:7 213:24	286:2 306:1,3
126:25 133:17	obtain 22:17 51:9	okay 6:7 7:2 9:21	215:2,5 217:3	opinion 9:10 10:15
134:20 135:24	115:14 215:15	10:2 12:17 13:13	220:24 221:5	10:17 29:11 48:17
137:15 138:2	243:17 244:23	13:19 14:1,14,15	229:23 232:5	53:4 83:23 85:3
139:8 141:21	obtained 85:6,9	16:19 17:1,5	235:13 250:5	85:20 92:2,7,25
145:6 157:1	93:21 262:7	21:15 22:6,8 24:1	251:5 253:15	93:6,13 94:2
164:23 165:10,24	277:20	24:8,15,19 25:6	257:19 263:21	100:18 128:18
166:17 168:24	obtaining 52:16	29:14,24 31:7	264:23 269:9	139:6 166:5,8,8
170:16 171:13	obviously 184:6	32:6,8 35:2,5,13	276:4 278:9,11	171:1,15 172:10
174:9 176:12	occasion 55:18 65:6	36:15 37:5,23	279:10 280:4,16	173:1 174:5,8,12
179:18 180:10	occasionally 111:2	38:20 39:2 41:23	281:2,6,11,17,19	174:16 176:10
220:5 240:8	125:2	43:9,15 44:14	285:11 286:6	177:19,23,25
251:18 254:9	occur 66:10 138:17	46:20 47:6,8,9,13	288:16 292:16	178:21,24 179:5,8
257:15 266:5	158:21 198:19	47:14 49:25 52:2	303:20	180:1,4 210:6
267:14 282:2	298:7,9	53:16 54:21 55:3	old 42:17,19 274:19	217:9,9,12,14
objection 27:19	occurred 17:14	58:6 61:25 63:16	292:7	218:2 220:1 221:6
83:11 240:19	70:22 132:22	63:19 64:7,12	older 140:3	221:11,17,22
262:12 270:16,19	139:3 147:15	66:18 67:20 70:7	Oliver 112:12	222:20 223:21,22
274:15 282:1	162:5 179:25	70:10 72:14 73:21	omit 140:25 231:1	224:15 225:19,25
objective 156:22	187:20 211:2	75:22 78:17 83:14	231:24	226:1 227:21
objects 268:16	242:20	85:25 88:1 95:7	omitted 200:15	229:6,9,17,21
obligation 148:18	occurring 181:11	96:24 97:21 98:14	203:8 230:11,23	230:24,25 231:8
obliterate 114:24	occurs 28:21	98:17 99:6 100:2	276:20	234:24 235:19
	•	-		

				Page 332
027.4.7.029.11		114:24	164:17 165:1	265:20 266:2
237:4,7 238:11	organized 275:18	overwrote 219:21	181:23 182:6	270:9
245:9 247:24	origin 194:21	o'clock 44:2	269:4 279:19	paucity 13:3
249:12,14 250:14	original 12:15,18 24:20 27:10 44:22	0 Clock 44.2	280:19 281:3	301:11
274:4 279:23		P	283:24	pause 46:9
281:20 282:16,16	58:2,3 71:21 74:7	package 103:21	paralegals 54:19	peer 96:17
283:1,19,19 286:7	76:22 82:23,25	147:21 273:4	parallel 110:25	peer-reviewed
287:3 288:3,4,18	169:22 217:21	packet 146:17	114:22	96:18,20,21
289:10,17,24	originally 305:5	202:10 276:20	Pardon 186:18	pending 141:1
292:8,9 293:8	ought 168:3	pad 36:21	parenthesis 269:24	255:21,23
295:17 297:8	outcome 155:13	page 3:10,13,17,18	part 35:11 36:25	Pennsylvania 1:13
302:5 303:8 304:8	162:1 241:21,23	105:25 106:8,19	59:20 76:19	4:12 253:19
opinions 10:10	305:6	129:11 131:10		255:22
14:11 15:17 16:8	outcomes 130:4	148:5,6 149:18	108:12 126:16	
26:15 29:3 48:12	outlined 143:4	159:5,6,11,12	137:12 161:22	people 16:23 121:22 126:8
51:12 71:15,18	outset 241:15,25	165:1 181:21,21	162:18 163:21	121:22 126:8
80:17 81:4 100:22	242:7 305:3	183:8,14,25 185:7	175:17 176:15	140:9 179:21
123:5 137:21	outside 15:23 41:8	1	178:17 186:5	i e
177:12 223:1	109:22 116:10	186:14,22,22	236:10 267:20	197:18 220:8
224:23 236:4	124:7 142:7	187:23 188:21	300:3	222:13 227:22
238:1 246:16	156:10 211:15	194:3,5,17 204:15	participated 215:8	237:5 238:16
247:19,22 248:16	213:4,9,21 224:6	209:23,25 232:2,6	particular 6:17	245:18 258:18,25
248:20 249:7,19	299:14	233:4 234:6	50:7 80:15 114:15	259:23 263:11,25
249:23 250:2	outstanding 189:7	265:14 278:9,12	115:13 125:3	283:4 291:21
251:16,22 252:15	189:14,23	278:13,17 279:9	140:22 156:8	295:1,10,18,21,24
252:18,21,23	out-of-context	279:12 281:19,21	157:8 223:19	296:17 297:24
253:5,9,11,25	166:20	282:18,19 283:24	302:11	298:1 303:4,11
254:2,7 255:25	overall 169:10	pages 3:7,8,11,14	particularly 61:2	304:12 305:10,17
256:4,6,7,12	280:25	3:15 9:2,3,24,25	88:16 199:24	305:18
264:7 280:10	overgeneralizati	12:10 30:25 60:10	216:15 223:15	percent 8:19 114:7
282:5,13,19,22	249:4	232:7 276:21	236:13 305:3	120:9 143:16
283:1,7,12,18,21	overlap 235:6	paid 78:18 252:12	parties 289:4	250:14
288:24	overnight 44:17	panel 95:21 127:22	parts 130:7,11	percentage 103:8
opportunity 21:24	207:2	238:3 241:2	passed 285:7	119:15 120:15
54:7 68:19 93:15	overrule 291:5	290:23	path 252:2	266:9
252:20 253:3	overruled 289:16	paper 30:11,18,25	patient 71:2,11	perfectly 298:4,15
255:17 257:25	295:8	31:18 37:2,10	103:24 118:6,10	period 48:19 63:15
295:2 296:10	overrules 305:21	52:11 138:23	120:14 195:20	82:16 108:16
304:2	overseeing 214:3	papers 46:1 66:20	196:10,12,16,22	119:14,24 128:8
opposed 113:23	oversight 210:3	116:24	196:23 197:9,20	136:6 152:2
option 257:1	212:24 214:9	paragraph 106:25	200:25 206:2	170:24 245:2
order 10:21 122:9	223:6,14 263:21	109:5 129:11,12	274:11	272:5,6
166:4 174:7	overturn 290:13	129:13 131:11,15	patients 71:8	Periodic 72:23 73:3
179:16 183:18	overview 3:15	145:5 148:10	132:14,25 197:13	148:18,20 149:5
234:20 236:7	94:15 250:16	149:7 150:2 159:6	202:14,21 203:3	175:6
organize 219:8	overwrite 111:4	159:11,16,22	204:21,22 205:21	permissible 142:13
8				
	•	-		A. C.

Videotaped

June 30, 2010

277:25	267:2 284:1	plaintiffs 5:3 6:4	123:21 141:2	178:2 213:23
permitted 137:11	Phase 97:3	14:20 15:5 30:4	142:16 157:11	218:21 243:6,7
277:6	Philadelphia 1:13	36:5 38:1,16	160:15 177:1	post 91:15 134:19
persistent 151:22	4:12 44:1 253:17	51:14 59:23 62:6	180:13,14,14	posted 134:17
178:6,14 284:13	255:23	62:10 63:2 80:10	185:4 193:12	135:1 272:18,21
person 95:16	phone 14:21 15:13	81:4 83:3,14	195:9 201:23	272:22
227:13 256:7	36:20 58:25	84:21 85:20 105:6	202:2,3,3 216:18	posting 134:22
262:9 263:6,24	242:14	116:15 117:11	233:22 236:20	135:3
275:3,7 295:16	photocopy 3:19	118:15 123:22	243:3 246:22,23	post-marketing
299:11	phrased 230:19	124:8 126:21	258:7,12 260:1	150:21 275:1,11
personnel 293:13	physician 88:8	137:23 146:4	263:17 266:23	potential 82:13
pertinent 153:14	274:11	212:11 213:3,21	269:25 272:25	87:11 119:3,4,6
pesticides 301:3	Ph.D 59:14 301:20	217:4 219:3	273:5 281:5	123:6 136:5
Pete 7:13 9:11 10:4	pick 259:14	228:25 236:3	286:14 287:22	156:10 241:21
12:2 14:21 25:25	picked 212:4	237:17 243:16	288:16 292:3	potentially 83:16
43:17,25 51:17	232:18	249:7,18,23 251:8	293:16,17 295:16	89:24 120:16
65:8 68:6 84:15	picture 66:17 82:6	261:11 264:18	298:24 299:4	131:22 173:18
154:3 160:23	103:22 136:15	267:21 268:3	302:25 305:20	194:25 217:7
223:5 241:3	169:10 175:13	276:17,22 304:17	pointed 54:24	224:19 270:4
242:13	piece 37:2 61:14	plaintiff's 37:16	points 23:24 130:24	273:18 291:20
pharma 25:13	65:24 66:14 68:10	53:7 66:19 122:21	145:4 170:4 202:9	practice 269:23
128:18 275:6	141:13 169:1,7	124:13 152:9	pooled 97:1	270:13 274:13
pharmaceutical	222:15	plan 26:24 160:10	population 120:8	practices 112:4,23
86:13 98:7 254:5	pieces 227:10 229:5	167:6,7 173:7,14	120:14 195:20	practicing 274:11
pharmacies 198:13	255:6	284:16,17,18	196:2,10,13,16,23	precipitate 298:13
202:6	piecing 68:9	286:18	196:23 201:1	precluded 74:13
pharmacist 62:16	pill 286:14	plans 48:22 228:17	205:3 206:2	precludes 74:5
102:25 197:9	pills 266:10 272:1	242:19	populations 197:20	prefer 251:19
pharmacodynamic	286:11,13	plant 61:9	201:12	255:8 271:13
97:3	place 61:21 63:14	play 199:12	portal 22:18	preference 221:12
pharmacovigilance	65:19 66:5,14	playing 95:13	position 157:24	preferred 244:11
3:20 10:7 70:13	92:20 107:24	Pleasant 2:4	165:22 177:9,11	260:6
82:2 86:8,13 87:4	136:22 152:4	please 4:19 5:13	230:4 287:23,24	preliminary 48:24
88:7,13 89:21	161:16 166:23	6:19 9:21 30:15	288:21 303:15	49:8 51:23 177:11
109:15,21 110:1	169:20 170:10,15	33:14 34:18 36:13	positions 218:18	195:10 209:4
112:3,24 137:20	170:23 210:21	41:18 48:4,7 49:9	possession 283:3,5	218:21 219:7,14
137:25 151:12,16	239:11	72:14 91:1 94:18	possibility 52:16	220:24 221:6
151:17 155:11	placebo 96:25 97:1	101:8 106:25	93:18 105:19	222:20,23 226:24
160:16 162:3,15	97:2	150:1 166:18	300:23	227:3 240:9
162:21 163:4	placed 68:17	180:2	possible 71:18	242:18 254:18
165:3 169:4,19	182:19 214:12	pleased 213:6	80:24 81:5,11	preparation 9:6
170:8 171:4,17	places 264:1	plus 114:12	170:11 194:22	17:4 36:18 148:12
205:9 213:15	plaintiff 2:2 38:10	point 6:25 9:11	236:18 275:2,7,12	181:3
214:11 219:13	238:1 259:10	28:4 52:13 94:1,4	possibly 58:24 60:8	prepare 7:6 12:9
223:13 240:12	261:23	109:8,8 114:17	68:2 93:8,9 157:2	13:15 23:1 52:22
		ALCO ESTABLE CONTRACTOR	72.274	

Videotaped

June 30, 2010

S4:15 56:4 prepared 18:4 26:6 38:10,16 47:20 58:50,16 47:20 58:50,16 47:20 58:50,16 47:20 58:50,16 47:20 58:55 90:61,6 47:20 58:55 90:61,6 47:20 58:55 90:61,6 47:20 58:55 90:61,6 47:20 58:55 90:61,6 47:20 58:55 90:61,6 47:20 58:55 90:61,6 47:20 58:55 90:61,6 47:20 58:55 90:61,6 47:20 58:51 90:61,6 47:20 58:51 90:61,6 47:20 58:51 90:61,6 47:20 58:51 90:61,6 47:20 58:51 90:61,6 47:20 58:51 90:61,6 47:20 58:51 90:61,6 47:20 58:51 90:61,6 47:20 58:51 90:61,2 59:51 90:61,2 9					Page 334
prepared 18:4 26:6 38:10,16 47:20 38:10,16 47:20 56:5,5 59:22 106:4,5 184:6 225:11 244:5 225:12 1244:5 225:12 1244:5 225:12 1244:5 225:12 1244:5 225:12 1244:5 225:12 124:5 225:13 104:5 225:13 104:5 225:17 283:10 220:22 293:21 220:22 293:21 220:22 293:21 220:22 293:21 220:22 293:21 220:22 293:21 220:22 293:21 220:22 293:21 220:22 293:21 220:22 293:21 220:22 293:21 220:22 293:21 220:22 293:21 220:24 207:6,15 220:24 207:6,10 220:24 207:6,15 220:24 207:6,10 220:24 207:6,15 220:24 207:6,10 220:24 207:6,10 220:24 207:6,10 220:24 207:6,10 220:24 207:6,10 220:24 207:6,10 220:24 207:6,10 220:	51.15 56.1	nross 16.5 22.22	nrobabilities	170:14 20 23	89.12 15 16 22
38:10,16 47:20 56:5,5 59:22 117:19 122:7,18 135:5 196:1,6,24 136:6,5 59:22 118:12 24:3 205:12 234:13 205:12 205:3,13 205:22 204:11,18 205:24 207:6,15 205:12 24:8 244:5 206:24 207:6,15 206:14 209:2,8,15 206:24 207:6,15 206:25 204:11,18 206:24 207:6,15 206:25 204:11,18 206:24 207:6,15 206:25 204:11,18 206:24 207:6,15 206:25 204:11,18 206:25 204:11,18 206:25 204:11,18 206:25 204:12 206:25 204:12 206:25 204:12 207:20 206:25 204:12 207:20 206:25 204:12 207:20 206:25 204:12 207:20 206:25 204:12 207:20 206:20 206:20 206:10 207:20 115:14 116:11,17 146:18,14 206:25 206:12 207:20 206:13 57:2 208:18 203:17 209:22 207:10,15 209:22 207:10,10 200:22 207:10,10 2		, A			, , ,
56:5,5 59:22 106:4,5 184:6 109:12 200:5,13 205:11 244:5 205:12 222 293:21 205:12 204:11,18 203:22 293:21 204:25 205:3,13 203:25 204:11,18 205:24 207:6,15 205:24 207:6,10 205:24 207:6,10 205:24 207:6,10 205:24 207:24 206:22 205:30 206:22 205:20 205:24 207				,	
18:12 200:5,13	,	l '		· '	
225:11 244:5 251:7 283:10 203:1,9,13,16,18 203:25 204:11,18 203:25 205:3,13 203:25 204:11,18 203:25 205:3,13 205:25 205:3,13 2		· '			
251:7 283:10 292:22 293:21 prepardeness 241:8 244:5 254:24 presponderance 50:17 prescribed 298:2 proceeding 256:10 proceed 293:6 proceeding 256:10 proceeding 256:10 proceeding 256:10 proceeding 256:10 proceed 293:6 proceeding 256:10 proceed 293:6 proceeding 256:10 proceed 293:6 proceeding 256:10 proceed 293:6 proceeding 256:10 proceeding 256:10 proceed 293:6 procee	· · · · · · · · · · · · · · · · · · ·				· · · · · · · · · · · · · · · · · · ·
292:22 293:21 preparedness 241:8 244:5 254:24 preparing 12:23 preponderance 50:17 prescribed 298:2 present 2:19 17:17 19:15 51:11 57:1 80:7 123:3,19 167:24 169:12 177:4 221:6 223:2 225:23 238:21 243:9 287:25 presentation 145:19 255:5 presentation 145:19 255:2 225:23 238:21 231:10 23:22 247:30 287:25 248:39 287:25 258:17 29:31 40:18 231:12 19:10,13 225:22 228:16 229:15 29:18 231:12 22:4 291:3 131:13 291:5 290:18 291:5 295:16 210:18 223:17 210:18 223:17 221:1 23:25 25:25 264:13,17 print 307:7,6 173:29 228:16 27 228:10 277:25 146:18,22,25 140:12,21 144:23 140:12,21 144:23 140:12,10,17,20 148:16 149:2 123:10 26:1 29:9 148:16 149:2 123:10 26:1 29:9 148:16 149:2 123:10 26:1 29:9 148:10 49:10 147:7,10,17,20 148:16 149:2 123:10 26:1 29:9 148:10 49:10 147:10,17,20 148:10 149:12 153:13 129:1 153:13 140:18 18:14 129:10,13 18:13 13:13 19:13 20:16:22 19:13 13:13 19:13 13:13 19:13 13:13 10:16:14 19:16:17 10:19 18:13 13:13 10:19			, <u> </u>		1
preparedness 241:8 244:5 204:25 205:3,13 125:13 129:2 258:10 277:25 146:18,22,25 146:18,22,25 147:7,10,10,17,20 147:7,10,10,17,20 147:7,10,10,17,20 147:7,10,10,17,20 147:7,10,10,17,20 147:7,10,10,17,20 147:7,10,10,17,20 147:7,10,10,17,20 147:7,10,10,17,20 147:7,10,10,17,20 147:7,10,10,17,20 147:7,10,10,17,20 147:7,10,10,17,20 147:7,10,10,17,20 147:7,10,10,17,20 147:7,10,10,17,20 147:7,10,10,17,20 148:16 149:2 177:70 179:00 148:16 149:2 179:00 148:16 149:2 179:00 188:11 129:10,13 170:223:12 171:83:23:14 188:11 129:10,13 189:12 223:22 223:10 26:1 29:9 23:10 26:1 29:9 23:10 26:1 29:9 23:117,18 232:1 199:22:15:15 23:11,11,18 23:1 199:22:15:15 23:11,11,18 23:1 199:22:15:15 23:11,17,18 23:1 199:22:15:15 23:11,11,18 23:1 23:11,11,18 23:1 23:11,11,18 23:1 23:11,11,18 23:1 23:11,11,18 23:1 23:11,11,18 23:1 23:11,11,18 23:1 23:11,11,18 23:1 23:11,11,18 23:1 23:11,11,18 23:1 23:11,11,18 23:1 23:11,11,18 23:1 23:11,11,18 23:1 23:11,11,18 23:1 23:11,11,18 23:1 23:11,11,18 23:1				1 ^	
241:8 244:5 254:24 208:14 209:22,81:5 209:22 273:6,12 209:22 283:6 229:13 274:5 231:12 29:10 231:17,18 232:1 231:17,18 23:2 231:17,18 23:2 231:17,18 23:2 231:17,18 23:2 231:17,18 23:2 231:17,18 23:2 231:17,18 23:2 231:17,18 23:2 231:17,18 23:2 231:17,18 23:2 231:17,18 23:2 231:17,18 23:2 231:17,18 23:	•	l , , , , , , , , , , , , , , , , , , ,			·
254:24				I	
preparing 12:23 preponderance 50:17 presoride 298:2 preseride 298:2 preseride 298:2 present 2:19 17:17 19:15 51:11 57:1 19:15 51:11 57:1 19:15 51:11 57:1 19:15 51:11 57:1 167:24 169:12 177:4 221:6 223:2 225:23 238:21 225:23 238:21 56:23 67:17 183:7 presentation 16:11,14 presented 7:14 13:1 15:19 16:6 17:12 18:9,24 21:1 23:25 25:25 presented 7:14 13:1 15:19 16:6 17:12 18:9,24 21:1 23:25 25:25 primary 13:3 26:18 17:13 18:13 19:10 17:14 18:24 19:10 18:13 19:10,13 225:22 28:16 229:13 13:13 23:10 26:1 29:9 23:10 26:1 29:9 23:11,7 18:23:1 23:10 26:1 29:9 23:11,7 18:23:1 23:10 26:1 29:9 23:11,7 18:23:1 152:25 15:12 17:12 18:24 22:1 23:10 26:1 29:9 23:11,7 18:23:1 152:25 15:12 19:32:14 18:13 17:1 19:15 23:15 16:12 18:23 17 22:14:19,19 216:5 22:1 288:20 29:13 13:13:3 20:12 20:19 20:13 13:13 20:10 26:1 29:9 23:11,7 18:23:1 23:10 26:1 29:9 23:11,7 18:23:1 152:25 15:12 19:32:14 18:23:17 23:10 26:1 29:9 23:11,7 18:23:1 152:25 15:12 19:32:14 18:23:17 22:14:19,19 216:5 22:1 28:20:19 22:13 13:13:3 22:1 22:22 22:5 28:22 25:16 22:5 13:10 23:10 26:1 29:9 23:11,18 23:17 23:10 26:1 29:9 23:11,18 23:17 23:10 26:1 29:9 23:11,18 23:17 23:10 26:1 29:9 23:11,18 23:17 23:10 26:1 29:9 23:11,18 23:17 23:10 26:1 29:9 23:11,18 23:17 23:11 20:10 26:1 22:12 22:12 22:12 22:12 22:12 22:12 22:12 22:12 22:12 22:	*	·			
preponderance 50:17 pressed 224:4 pressured 284:11 pretty 50:9 196:17 19:15 51:11 57:1 99:4 225:8 303:17 232:5 233:1 34:12 35:3 60:18 232:19,23,24 25:22 228:16 24:9 prevent 107:24 previously 16:22 25:22 228:16 30:19 23:21,24,25 23:25 23:31 34:12 35:3 60:18 23:19,23,24 25:22 228:23 238:21 prevent 107:24 previously 16:22 56:23 67:17 183:7 primarily 171:2 primary 13:3 26:18 81:1 102:2 169:21 171:8,9 234:25 presentation 16:11,14 print 30:7,16 113:9 printed 7:8,17 9:5 13:1 15:19 16:6 17:12 18:9,24 27:12 13:2 55:2 55:17 12:13 12:2 227:10,15,16 22:17 227:6,10 230:3 245:25 249:12 227:6,10 230:3 245:25 249:12 250:17 251:12 250:27 250:29 116:29:13 13:1 20:16 22:18 224:20 227:6,9 303:10,19 305:21 presenting 123:17 218:5 288:17 291:9 292:4 private 98:5,6 probabilistic 16:62 167:3 63:10 64:18 6:2 25:13 23:0 52:13 16:5 probabilistic 16:0 20 283:3 16:4:10 64:20 165:17,19 16:15;23 13:0 25:13 20:22 25:33 25:3 product 15:48 224:20 291:9 292:4 private 98:5,6 probabilistic 16:0 20 283:3 16:4:10 64:20 165:17,19 16:22 13:20 20:22 25:33 1 22:13 28:20 29:11 12:23 16:5 produced 15:16 16:15;26 23:12 28:13 20:22 27:24 27:24 28:17 28:5 288:17 291:9 292:4 probabilistic 16:21 67:3 46:18 6:2 29:11,12 32:20 29:11 12:23 16:25 20:19 product 15:16 16:15;16 16:21 67:3 16:22 26:22 25:63:3,68 25:13 26:23 29:11,12 32:20 29:11,12	— -		1	, <u>.</u>	
50:17 prescribed 298:2 present 2:19 17:17 pressed 224:4 pressured 284:11 pretty 50:9 196:17 23:22 228:16 stor.1 press 22:22 228:16 pressured 284:11 pretty 50:9 196:17 23:22 228:16 stor.1 pressed 224:4 pressured 284:11 pretty 50:9 196:17 23:22 228:16 stor.1 pressed 224:4 pressured 284:11 pretty 50:9 196:17 23:22 23:25 233:1 34:12 35:3 60:18 23:21,24,25 23:21 23:22 23:25 23:31 34:12 35:3 60:18 23:21,24,25 23:21 23:22 228:16 pressured 284:11 pretty 50:9 196:17 23:22 23:25 23:31 34:12 35:3 60:18 23:21,24,25 23:22 228:16 pressured 284:11 pretty 50:9 196:17 23:22 23:25 23:31 274:5 pross.1 pressured 284:11 pretty 50:9 196:17 23:22 23:25 23:31 274:5 pross.1 pressured 284:11 pretty 50:9 196:17 23:22 23:25 23:31 274:5 pross.1 pressured 284:11 pretty 50:9 196:17 23:22 23:25 23:31 274:5 pross.1 press.1 pressured 284:11 pretty 50:9 196:17 23:22 23:25 23:31 274:5 pross.1 press.1 p	,		· · · · · · · · · · · · · · · · · · ·		
prescribed 298:2 present 2:19 17:17 19:15 51:16 57:18 29:19 15:51:1 57:1 80:7 123:3,19 167:24 169:12 177:4 221:6 223:2 225:23 238:21 243:9 287:25 225:23 238:21 243:9 287:25 238:21 255:3 238:21 243:9 287:25 255:5 primary 13:3 26:18 81:1 102:2 169:21 171:8,9 234:25 270:3 305:9 presentations 16:11,14 print 30:7,16 113:9 problems 76:12 18:9,24 21:1 23:25 25:25 23:8 10:10 20:10 20:21 25:17 129:3 140:18 170:19 177:22 217:10,15,16 221:18 224:20 171:22 217:10,15,16 221:18 224:20 217:20:17 25:12 217:10,15,16 221:18 224:20 217:20:17 25:12 217:10,15,16 221:18 224:20 217:20:17 25:12 217:10,15,16 221:18 224:20 217:20:17 25:12 217:10,15,16 221:18 224:20 217:20:17 25:112 250:17 251:12 250:17 251:12 250:17 251:12 250:17 251:12 250:17 251:12 250:17 251:12 250:17 251:12 250:17 251:12 250:17 251:12 250:17 251:12 250:17 251:12 250:17 251:12 250:17 251:12 250:17 251:12 250:19 292:4 pressured 284:11 pretty 50:9 196:17 232:2 28:16 232:10 26:1 29:9 34:12 35:3 60:18 90:3,14 92:10 233:14,2 25:3 30:14 90:3,14 92:10 233:14,7 255:4 products 19:5 40:18 18:4 196:7 214:19,19 216:5 216:25 220:19 29:18 22:23 20:18 22:23 20:18 20:19 303:1 21:13:13:13:13:13:13:13:13:13:13:13:13:13	^ -			ł	
present 2:19 17:17 pretty 50:9 196:17 232:25 233:1 34:12 35:3 60:18 232:19,23,24 19:15 51:11 57:1 19:4 225:8 303:17 288:25 290:18 158:15 161:14 233:21,24,25 167:24 169:12 277:4 221:6 223:2 225:23 238:21 232:19,23,24 233:21,24,25 225:23 238:21 225:23 238:21 225:23 67:17 183:7 291:5 295:16 181:4 196:7 270:41:19,19 216:5 234:1,7 255:4 234:1,7 255:4 234:1,7 255:4 234:1,7 255:4 233:21,24,25 235:21 286:18 251:13,18 216:12 <td< td=""><td></td><td>, -</td><td>•</td><td></td><td>ł</td></td<>		, -	•		ł
19:15 51:11 57:1 80:7 123:3,19 167:24 169:12 177:4 221:6 223:2 225:23 238:21 243:9 287:25 303:7 presentation 145:19 255:5 presentations 16:11,14 presented 7:14 13:1 15:19 16:6 17:12 18:9,24 21:1 23:25 25:25 17:18,9 234:25 21:10 23:31 18:1 10:19 16:6 17:12 18:9,24 21:1 23:25 25:25 17:18,9 234:25 21:10 23:3 140:18 170:19 177:22 217:10,15,16 221:18 224:20 227:6,10 230:3 227:13 16:5 227:13 13:13 230:12 244:19,19 216:5 24:129,12 22:13 252:1 288:20 295:5 270:3 305:9 270:3	l -	*			·
80:7 123:3,19 167:24 169:12 177:4 221:6 223:2 225:23 238:21 235:23 238:21 236:36 7:17 183:7 presentation 145:19 255:5 presentations 16:11,14 presented 7:14 13:1 15:19 16:6 17:12 18:9,24 21:1 23:25 25:25 51:7 129:3 140:18 170:19 177:22 217:10,15,16 221:18 224:20 227:6,10 230:3 227:6,10 230:3 227:6,10 230:3 245:25 249:12 250:17 251:12 250:17 251:12 250:27 251:10,11 250:9 305:21 251:18 288:17 291:9 292:4 80:7 107:24 291:9 292:4 288:25 290:18 291:5 295:16 303:17 prevent 107:24 291:5 295:16 303:17 proviously 16:22 301:19 303:1 291:19 303:1 291:19 303:1 292:5 220:19 202:19 220:19 202:19 202:4 215:20 30:11 31:13 210:18 223:17 227:5 235:8 237:5 227:5 235:8 237:5 227:5 235:8 237:5 227:5 235:8 237:5 227:5 235:8 237:5 227:5 235:8 237:5 227:5 235:8 237:5 227:5 235:8 237:5 227:5 235:8 237:5 227:5 235:8 237:5 227:3 235:8 237:5 227:3 235:8 237:5 227:3 235:9 227:5 235:8 237:5 227:5 235:8 237:5 227:5 235:8 237:5 227:5 235:8 237:5 227:5 235:8 237:5 227:5 235:8 237:5 227:5 235:8 237:5 227:3 238:8 237:5 227:3 238:8 237:5 227:3 238:8 237:5 227:3 238:8 237:5 227:3 238:8 237:5 227:3 238:8 237:5 227:3 238:8 237:5 228:12 20 214:17 229:19 20:24 229:19 20:24 229:19 20:23 229:5 29:13 13:13 210:18 223:17 220:13 220:14 20:12 20:12 20:19 220:14:17 106:4 220:14 20:12 220:19 220:19 24:16:25 220:19 220:16:25 220:1	l -	, - -		<u> </u>	
167:24 169:12 prevent 107:24 291:5 295:16 181:4 196:7 production 276:17 177:4 221:6 223:2 256:23 67:17 183:7 problem 42:16 301:19 303:1 214:19,19 216:5 56:12 82:14 88:8 243:9 287:25 primarly 171:2 primary 13:3 26:18 129:13 131:13 252:1 288:20 89:20 94:20 95:3 presentation 145:19 255:5 171:8,9 234:25 227:5 235:8 237:5 227:5 235:8 237:5 processed 61:23 product's 269:21 product's 269:21 <t< td=""><td></td><td></td><td></td><td>l '</td><td></td></t<>				l '	
177:4 221:6 223:2 previously 16:22 301:19 303:1 214:19,19 216:5 products 19:5 225:23 238:21 235:23 238:21 primarily 171:2 probing 122:23 216:25 220:19 25:12 82:14 88:8 303:7 primary 13:3 26:18 81:1 102:2 169:21 252:1 288:20 89:20 94:20 95:3 303:7 primary 13:3 26:18 129:13 131:13 295:5 89:20 94:20 95:3 presentation 145:19 255:5 171:8,9 234:25 227:5 235:8 237:5 62:5 product's 269:21 presented 7:14 print 30:7,16 113:9 printed 7:8,17 9:5 30:22 135:10 30:22 135:10 30:22 135:10 58:17 63:14 65:19 progress 27:13,16 58:17 63:14 65:19 progress 27:13,16 progress 27:13,16 66:5 70:13 82:15 progress 27:13,16 66:5 70:13 82:15 progress 27:13,16 58:17 63:14 65:19 progress 27:13,16 66:5 70:13 82:15 progress 27:13,16 66:5 70:13 82:15 progress 27:13,16 66:5 70:13 82:15 project 65:14 97:1 project 65:	· · · · · · · · · · · · · · · · · · ·		}		*
225:23 238:21		1 ~		1	1 -
243:9 287:25 303:7 presentation 145:19 255:5 presentations 16:11,14 print 30:7,16 113:9 presented 7:14 13:1 15:19 16:6 13:1 15:19 16:6 17:12 18:9,24 17:12 18:9,24 21:1 23:25 25:25 51:7 129:3 140:18 170:19 177:22 217:10,15,16 221:18 224:20 217:10,15,16 221:18 224:20 217:10,15,16 221:18 224:20 217:10,15,16 221:18 224:20 217:10,15,16 221:18 224:20 217:10,15,16 221:18 224:20 217:10,15,16 221:18 224:20 217:10,15,16 221:18 224:20 217:10,15,16 221:18 224:20 217:10,15,16 221:18 224:20 217:10,15,16 221:18 224:20 217:10,15,16 221:18 224:20 217:10,15,16 221:18 224:20 217:10,15,16 221:18 224:20 217:10,15,16 221:18 224:20 217:10,15,16 221:18 224:20 217:10,15,16 221:18 224:20 217:10,15,16 221:18 224:20 227:6,10 230:3 245:25 249:12 250:17 251:12 250:17 251:12 250:17 251:12 250:17 251:12 250:27 255:10,11 256:9 303:10,19 305:21 presenting 123:17 218:5 288:17 291:9 292:4 probabilistic problem 42:16 129:13 131:13 210:18 223:17 problem 42:16 129:13 131:13 210:18 223:17 problem 42:16 129:13 131:13 210:18 223:17 processed 61:23 processes 27:13,16 58:17 66:19 65:19 58:17 66:5 70:13 82:15 progrems 27:9 166:5 70:13 82:15 progress 39:8 product's 269:21 profle 241:20 255:9 processes 27:13,16 66:5 70:13 82:15 progress 39:8 proplem 42:16 129:13 131:13 210:18 223:17 227:5 235:8 237:5 270:3 305:9 processes 27:13,16 66:5 70:13 82:15 progress 39:8 proplem 42:16 129:13 131:13 210:18 223:17 227:5 235:8 237:5 270:3 305:9 processed 61:23 processes 27:13,16 66:5 70:13 82:15 progress 39:8 proplem 42:16 129:13 131:13 210:18 223:17 227:5 235:8 237:5 270:3 305:9 processes 61:23 processes 27:13,16 66:5 70:13 82:15 progress 39:8 proplem 42:16 129:13 131:13 210:160:4 141:10 210:21 120:14:17 287:4 289:20 processing 186:25 produce 65:12 proplem 42:16 129:13 131:13 210:160:4 141:10 210:21 120:14:17 287:4 289:20 processing 186:25 produce 65:12 148:22 278:8 produce 4:216 129:13 13:20 166:5 70:13 82:15 progress 39:8 proplem 42:16 129:13 13:20 160:4 141:10 210:21 148:22 278:8 produce 4:21 148:22 278:8 produce 4:18 15:1 16:15 17 15:19 13:20 166:9 128:20 166:9 128		1 -	,		1 -
303:7 primary 13:3 26:18 129:13 131:13 295:5 processed product's 269:21 145:19 255:5 171:8,9 234:25 227:5 235:8 237:5 227:5 235:8 237:5 62:5 processed 255:9 presentations 264:13,17 print 30:7,16 113:9 problems 76:12 58:17 63:14 65:19 16:16 178:14 13:1 15:19 16:6 30:22 135:10 30:22 135:10 131:20 160:4 66:5 70:13 82:15 progress 39:8 17:12 18:9,24 307:19 180:15 230:5 211:20 214:17 processing 186:25 prohibitive 28:24 170:19 177:22 30:17,20 91:4,12 90:17,20 91:4,12 285:23 procedure 115:16 148:22 278:8 proposal 58:17,20 59:3 227:6,10 230:3 191:5 299:25 172:18 272:2 145:24 146:7 provide 27:13 51:16 58:23 62:11 250:17 251:12 255:1,14,19 166:9 128:8,17 166:9 178:23 58:17 60:19 61:5 58:17 60:19 61:5 254:19 private 98:5,6 141:19 143:23 product 1:5 48 236:17 237:6 255:9 provided 9:22 25:13 26:8,9,22 29:19 292:4 <td></td> <td></td> <td></td> <td></td> <td>89:20 94:20 95:3</td>					89:20 94:20 95:3
presentation 81:1 102:2 169:21 210:18 223:17 processed 61:23 profile 241:20 255:9 presentations 264:13,17 print 30:7,16 113:9 problems 76:12 58:17 63:14 65:19 program 27:9 16:16:16 178:14 presented 7:14 printed 7:8,17 9:5 30:22 135:10 131:20 160:4 58:17 63:14 65:19 program 27:9 16:16 178:14 progress 39:8 profibitive 28:24 progress 39:8 problems 76:12 131:20 160:4 58:17 63:14 65:19 progress 39:8 problems 76:12 141:10 210:21 progress 39:8 problems 76:12 141:10 210:21 progress 39:8 problems 76:12 141:10 210:21 propress 39:8 problems 76:12 141:10 210:21 propress 39:8 problems 76:12 141:10 210:21 241:10 241:17 project 65:14 97:1		, <u>-</u>	1 -		
145:19 255:5 171:8,9 234:25 227:5 235:8 237:5 62:5 255:9 presentations 264:13,17 print 30:7,16 113:9 problems 76:12 58:17 63:14 65:19 16:16 178:14 presented 7:14 printed 7:8,17 9:5 30:22 135:10 131:20 160:4 66:5 70:13 82:15 161:16 178:14 17:12 18:9,24 307:19 180:15 230:5 211:20 214:17 project 65:14 97:1 21:1 23:25 25:25 prints 110:13 237:20 245:14 287:4 289:20 promised 29:6 51:7 129:3 140:18 prior 63:3,11 89:12 90:17,20 91:4,12 285:23 produce 65:12 proposal 58:17,20 21:18 224:20 115:23 116:5 115:19 133:21 148:22 278:8 propounded 307:7 227:6,10 230:3 191:5 299:25 pristine 151:19 procedures 97:14 160:20 283:3 propounded 307:7 255:9 303:10,19 125:1,14,19 136:21 139:5 produces 99:13 produce 1:5 4:8 256:9 303:10,19 254:19 144:7,13,17 58:17 60:19 61:5 284:1 256:9 303:10,29 private 98:5,6 141:19 143:23 58:17 60:19 61:5 284:1 251:1 2285:28 product 1:5 4:8 286:19 63:27,22 63:3,6,8		1	l .		
presentations 264:13,17 270:3 305:9 processes 27:13,16 program 27:9 16:11,14 print 30:7,16 113:9 problems 76:12 58:17 63:14 65:19 16:16 178:14 13:1 15:19 16:6 30:22 135:10 171:25 173:5 141:10 210:21 progress 39:8 17:12 18:9,24 307:19 180:15 230:5 211:20 214:17 project 65:14 97:1 21:1 23:25 25:25 prints 110:13 237:20 245:14 287:4 289:20 project 65:14 97:1 17:19 177:22 90:17,20 91:4,12 285:23 produce 65:12 proposal 58:17,20 21:18 224:20 115:23 116:5 15:19 133:21 148:22 278:8 proposal 58:17,20 227:6,10 230:3 191:5 299:25 pristine 151:19 procedures 97:14 160:20 283:3 propounded 307:7 250:17 251:12 privacy 124:23 106:9 122:8,17 286:19 63:2 71:22 137:24 256:9 303:10,19 254:19 144:7,13,17 58:17 60:19 61:5 284:1 presenting 123:17 privy 85:5 122:8 product 1:5 4:8 286:19 284:1 produces 99:13 producet 1:5 4:8 284:1 <td></td> <td></td> <td></td> <td>, .</td> <td>1 ~</td>				, .	1 ~
16:11,14 print 30:7,16 113:9 problems 76:12 58:17 63:14 65:19 161:16 178:14 presented 7:14 13:1 15:19 16:6 30:22 135:10 131:20 160:4 66:5 70:13 82:15 prophibitive 28:24 17:12 18:9,24 307:19 180:15 230:5 211:20 214:17 project 65:14 97:1 21:1 23:25 25:25 prints 110:13 237:20 245:14 287:4 289:20 project 65:14 97:1 17:19 177:22 90:17,20 91:4,12 285:23 produce 65:12 project 65:12 prophibitive 28:24 21:18 224:20 15:23 116:5 15:19 133:21 148:22 278:8 project 65:12 prophibitive 28:24 227:6,10 230:3 191:5 299:25 pristine 151:19 procedure 115:16 148:22 278:8 produced 18:5 propounded 307:7 256:9 303:10,19 private 98:5,6 141:19 143:23 26:19 166:9 122:8,17 286:19 produces 99:13 51:16 58:23 62:11 236:17 237:6 284:1 166:9 178:25 236:17 237:6 284:1 166:9 178:25 254:19 166:2 167:3 62:22,25 63:3,6,8 25:13 26:8,9,22 25:13 26:8,9,22 25:13 26:8,9,22 25:13 26:8,9,22		l '	and the second s		program 27:9
presented 7:14 printed 7:8,17 9:5 131:20 160:4 66:5 70:13 82:15 progress 39:8 17:12 18:9,24 307:19 180:15 230:5 211:20 214:17 project 65:14 97:1 21:1 23:25 25:25 prints 110:13 237:20 245:14 287:4 289:20 project 65:14 97:1 17:10;19 177:22 90:17,20 91:4,12 285:23 produce 65:12 properly 232:15 217:10,15,16 93:22 96:19 115:7 115:29 133:21 148:22 278:8 proposal 58:17,20 227:6,10 230:3 191:5 299:25 pristine 151:19 procedure 115:16 produced 18:5 project 65:12 proposal 58:17,20 250:17 251:12 pristine 151:19 procedures 97:14 160:20 283:3 51:16 58:23 62:11 256:9 303:10,19 125:1,14,19 136:21 139:5 produce 59:13 166:9 178:25 305:21 private 98:5,6 141:19 143:23 product 1:5 4:8 236:17 237:6 254:19 privy 85:5 122:8 160:18 161:7 62:22,25 63:3,6,8 25:13 26:8,9,22 29:19 292:4 probabilistic 166:2 167:3 63:10 64:1 86:2 29:11,12 32:20	l -		i		
13:1 15:19 16:6 30:22 135:10 171:25 173:5 141:10 210:21 prohibitive 28:24 17:12 18:9,24 307:19 180:15 230:5 211:20 214:17 project 65:14 97:1 21:1 23:25 25:25 prints 110:13 237:20 245:14 287:4 289:20 project 65:14 97:1 51:7 129:3 140:18 prior 63:3,11 89:12 265:14 284:21 processing 186:25 project 65:12 170:19 177:22 90:17,20 91:4,12 90:17,20 91:4,12 procedure 115:16 produce 65:12 proposal 58:17,20 221:18 224:20 191:5 299:25 pristine 151:19 procedures 97:14 160:20 283:3 propounded 307:7 225:2 249:12 privacy 124:23 106:9 122:8,17 286:19 51:16 58:23 62:11 250:17 251:12 private 98:5,6 141:19 143:23 produces 99:13 51:16 58:23 62:11 256:9 303:10,19 254:19 144:7,13,17 58:17 60:19 61:5 284:1 presenting 123:17 prov 300:5 164:20 165:17,19 62:22,25 63:3,6,8 25:13 26:8,9,22 291:9 292:4 probabilistic 166:2 167:3 63:10 64:1 86:2 29:11,12 32:20	,	l -	(*		progress 39:8
17:12 18:9,24 307:19 180:15 230:5 211:20 214:17 project 65:14 97:1 21:1 23:25 25:25 prints 110:13 237:20 245:14 287:4 289:20 promised 29:6 51:7 129:3 140:18 prior 63:3,11 89:12 265:14 284:21 processing 186:25 properly 232:15 170:19 177:22 90:17,20 91:4,12 285:23 produce 65:12 proposal 58:17,20 21:18 224:20 93:22 96:19 115:7 115:23 116:5 115:19 133:21 148:22 278:8 proposal 58:17,20 227:6,10 230:3 191:5 299:25 pristine 151:19 procedures 97:14 160:20 283:3 provide 27:13 250:17 251:12 privacy 124:23 106:9 122:8,17 286:19 63:2 71:22 137:24 252:2 255:10,11 125:1,14,19 136:21 139:5 produces 99:13 166:9 178:25 256:9 303:10,19 254:19 private 98:5,6 141:19 143:23 product 1:5 4:8 286:19 284:1 218:5 288:17 pro 300:5 166:2 167:3 63:20 63:3,6,8 25:13 26:8,9,22 29:11,12 32:20 29:11,12 32:20		ı ~	i		
21:1 23:25 25:25 prints 110:13 237:20 245:14 287:4 289:20 promised 29:6 51:7 129:3 140:18 prior 63:3,11 89:12 265:14 284:21 processing 186:25 properly 232:15 170:19 177:22 90:17,20 91:4,12 285:23 produce 65:12 proposal 58:17,20 21:18 224:20 115:23 116:5 115:19 133:21 148:22 278:8 proposal 58:17,20 227:6,10 230:3 191:5 299:25 pristine 151:19 procedures 97:14 160:20 283:3 provide 27:13 250:17 251:12 privacy 124:23 106:9 122:8,17 286:19 produces 99:13 51:16 58:23 62:11 252:2 255:10,11 125:1,14,19 136:21 139:5 produce 1:5 4:8 236:17 237:6 256:9 303:10,19 254:19 private 98:5,6 141:19 143:23 product 1:5 4:8 236:17 237:6 254:19 privy 85:5 122:8 pro 300:5 164:20 165:17,19 62:22,25 63:3,6,8 25:13 26:8,9,22 291:9 292:4 probabilistic 166:2 167:3 63:10 64:1 86:2 29:11,12 32:20			1	l '	1 =
51:7 129:3 140:18 prior 63:3,11 89:12 265:14 284:21 processing 186:25 properly 232:15 170:19 177:22 90:17,20 91:4,12 285:23 produce 65:12 proposal 58:17,20 217:10,15,16 93:22 96:19 115:7 procedure 115:16 148:22 278:8 propounded 307:7 221:18 224:20 115:23 116:5 115:19 133:21 produce 18:5 propounded 307:7 227:6,10 230:3 191:5 299:25 pristine 151:19 procedures 97:14 160:20 283:3 provide 27:13 250:17 251:12 privacy 124:23 125:1,14,19 136:21 139:5 286:19 63:2 71:22 137:24 252:2 255:10,11 125:1,14,19 136:21 139:5 produces 99:13 produces 99:13 166:9 178:25 305:21 private 98:5,6 141:19 143:23 58:17 60:19 61:5 284:1 presenting 123:17 proy 85:5 122:8 160:18 161:7 61:15,21 62:3,11 provided 9:22 21:9 292:4 probabilistic 166:2 167:3 63:10 64:1 86:2 29:11,12 32:20	-		1	287:4 289:20	
170:19 177:22 90:17,20 91:4,12 285:23 produce 65:12 proposal 58:17,20 217:10,15,16 93:22 96:19 115:7 procedure 115:16 148:22 278:8 59:3 221:18 224:20 115:23 116:5 115:19 133:21 produced 18:5 propounded 307:7 227:6,10 230:3 191:5 299:25 pristine 151:19 procedures 97:14 160:20 283:3 51:16 58:23 62:11 250:17 251:12 privacy 124:23 106:9 122:8,17 286:19 produces 99:13 51:16 58:23 62:11 252:2 255:10,11 125:1,14,19 136:21 139:5 produces 99:13 166:9 178:25 256:9 303:10,19 254:19 144:7,13,17 58:17 60:19 61:5 284:1 218:5 288:17 pro 300:5 164:20 165:17,19 62:22,25 63:3,6,8 25:13 26:8,9,22 29:19 292:4 probabilistic 166:2 167:3 63:10 64:1 86:2 29:11,12 32:20	1	[4	1	processing 186:25	
217:10,15,16 93:22 96:19 115:7 procedure 115:16 148:22 278:8 59:3 221:18 224:20 115:23 116:5 115:19 133:21 produced 18:5 propounded 307:7 227:6,10 230:3 191:5 299:25 172:18 272:2 145:24 146:7 provide 27:13 245:25 249:12 250:17 251:12 privacy 124:23 106:9 122:8,17 286:19 51:16 58:23 62:11 252:2 255:10,11 125:1,14,19 136:21 139:5 produces 99:13 166:9 178:25 256:9 303:10,19 private 98:5,6 141:19 143:23 product 1:5 4:8 236:17 237:6 305:21 254:19 144:7,13,17 58:17 60:19 61:5 284:1 presenting 123:17 privy 85:5 122:8 160:18 161:7 61:15,21 62:3,11 provided 9:22 218:5 288:17 291:9 292:4 probabilistic 166:2 167:3 63:10 64:1 86:2 29:11,12 32:20					
221:18 224:20 115:23 116:5 115:19 133:21 produced 18:5 propounded 307:7 227:6,10 230:3 191:5 299:25 172:18 272:2 produced 18:5 provide 27:13 245:25 249:12 pristine 151:19 procedures 97:14 160:20 283:3 51:16 58:23 62:11 250:17 251:12 privacy 124:23 125:1,14,19 136:21 139:5 produces 99:13 63:2 71:22 137:24 256:9 303:10,19 private 98:5,6 141:19 143:23 producet 1:5 4:8 236:17 237:6 305:21 254:19 144:7,13,17 58:17 60:19 61:5 284:1 presenting 123:17 privy 85:5 122:8 166:2 167:3 62:22,25 63:3,6,8 25:13 26:8,9,22 291:9 292:4 probabilistic 166:2 167:3 63:10 64:1 86:2 29:11,12 32:20		1 '		1 ^	
227:6,10 230:3 191:5 299:25 172:18 272:2 145:24 146:7 provide 27:13 245:25 249:12 250:17 251:12 privacy 124:23 106:9 122:8,17 160:20 283:3 51:16 58:23 62:11 252:2 255:10,11 125:1,14,19 136:21 139:5 produces 99:13 166:9 178:25 256:9 303:10,19 private 98:5,6 141:19 143:23 product 1:5 4:8 236:17 237:6 305:21 privy 85:5 122:8 160:18 161:7 61:15,21 62:3,11 provided 9:22 218:5 288:17 pro 300:5 164:20 165:17,19 62:22,25 63:3,6,8 25:13 26:8,9,22 291:9 292:4 probabilistic 166:2 167:3 63:10 64:1 86:2 29:11,12 32:20			1 -	produced 18:5	propounded 307:7
245:25 249:12 pristine 151:19 procedures 97:14 160:20 283:3 51:16 58:23 62:11 250:17 251:12 privacy 124:23 106:9 122:8,17 286:19 63:2 71:22 137:24 252:2 255:10,11 125:1,14,19 136:21 139:5 produces 99:13 166:9 178:25 256:9 303:10,19 254:19 141:19 143:23 product 1:5 4:8 236:17 237:6 254:19 160:18 161:7 58:17 60:19 61:5 284:1 218:5 288:17 pro 300:5 164:20 165:17,19 62:22,25 63:3,6,8 25:13 26:8,9,22 291:9 292:4 probabilistic 166:2 167:3 63:10 64:1 86:2 29:11,12 32:20					provide 27:13
250:17 251:12	-		li .	· ·	51:16 58:23 62:11
252:2 255:10,11 256:9 303:10,19 305:21 presenting 123:17 218:5 288:17 291:9 292:4 125:1,14,19 private 98:5,6 254:19 privy 85:5 122:8 pro 300:5 probabilistic 136:21 139:5 141:19 143:23 144:7,13,17 160:18 161:7 160:18 161:7 166:2 167:3 produces 99:13 166:9 178:25 236:17 237:6 284:1 provided 9:22 25:13 26:8,9,22 29:11,12 32:20		1 -	; -	286:19	63:2 71:22 137:24
256:9 303:10,19 private 98:5,6 141:19 143:23 product 1:5 4:8 236:17 237:6 305:21 254:19 144:7,13,17 58:17 60:19 61:5 284:1 presenting 123:17 privy 85:5 122:8 160:18 161:7 61:15,21 62:3,11 provided 9:22 25:13 26:8,9,22 25:13 26:8,9,22 291:9 292:4 probabilistic 166:2 167:3 63:10 64:1 86:2 29:11,12 32:20		, <u> </u>	, · · · · · · · · · · · · · · · · · · ·	produces 99:13	166:9 178:25
305:21			141:19 143:23	product 1:5 4:8	236:17 237:6
presenting 123:17 privy 85:5 122:8 160:18 161:7 61:15,21 62:3,11 provided 9:22 218:5 288:17 164:20 165:17,19 62:22,25 63:3,6,8 25:13 26:8,9,22 291:9 292:4 166:2 167:3 63:10 64:1 86:2 29:11,12 32:20		. –		1 ^	284:1
218:5 288:17	•		· '	61:15,21 62:3,11	
291:9 292:4 probabilistic 166:2 167:3 63:10 64:1 86:2 29:11,12 32:20	, - -	1 -			
	ř	1 -	1	•	
	i	l -		86:21 88:5,9	52:8 58:16 60:20
			ĺ		

Videotaped

June 30, 2010

				
61:11 65:25 70:17	pull 126:17 146:19	qualifier 88:1	171:12 172:9,10	306:1,2 307:7
74:17,19 75:1	277:8 293:11	qualify 105:16	189:23 190:6	question-and-ans
79:5 80:21 81:2	pulled 120:12	126:18 245:7	191:7,11,14 192:9	23:15
92:5,16 94:1,10	287:7	quality 26:24 76:6	198:6,9 200:1	quickly 32:17
95:18 101:17	pulling 126:19	88:8 97:13,17	203:9 209:21	152:15 175:2
	157:17 160:7	102:7 120:21,21	211:16 212:6	192:8 227:18
103:14 119:10,17	punched 67:13	130:3 162:2,14,14	213:8,17,20	quietly 225:15
119:19,22 123:14	•	l ' '	216:18,18 218:13	quietry 223.13 quite 112:19
124:7 137:1,19	purpose 122:1	162:17,21,21,24	223:20 227:5	230:18
138:3,6 139:1	purposes 41:6 115:2 194:16	219:10,12 224:18 245:8 249:3	239:13 240:20	quotation 278:13
142:18 147:19,23		263:11 265:14	248:9 254:13,14	278:15
149:23 150:4,9	pursuant 1:17		1	quotations 182:18
152:12 163:11,13	pursue 117:4 239:5	269:21 280:3,9	257:18,21,21,22	quota 161:12 162:8
168:22 171:6	pursuing 238:21	284:2,8	258:12 259:3,19	_
177:1,8 179:16,19	pursuit 303:7	quantify 117:22	271:24 274:7	162:9,13 182:8
180:25 195:22	put 34:8 39:19	quantitate 272:1	276:9 278:1	186:14
217:23,23 220:15	53:12 69:6 82:5	quantitative	280:14 281:16	quoted 187:22,23
220:20,21 223:3	96:1 107:24	114:12 120:24	282:21 285:6,22	quotes 12:14 34:6
235:10 248:5,7	111:11 115:2	quarter 15:12	290:13,15 292:16	196:18
253:11 263:2,3	117:8 138:16	284:6	293:2,4 296:17	quoting 184:13
270:24 278:3	143:10 153:14	question 6:11 7:25	297:15,17,23	R
284:16 289:14,15	156:18,19 160:12	14:8,8,13,14	300:15,16 302:1	$\overline{\mathbf{R}}$ 1:15
293:10	161:16 169:3,9	17:24,24 19:11	questioned 205:19	raise 153:13 251:15
providing 87:22	189:24 192:16,16	20:25 21:6 23:13	225:6 260:5	1
198:25 218:17	192:23,25 196:8	24:16 38:13 39:3	questioning 15:23	raised 102:7,12
provision 211:21	199:11 205:24,25	46:10 47:11,13	17:20 18:4,15	166:15 179:20
PSUR 148:12,22	230:9,10 231:2,7	52:2,3 66:25	22:21 43:8 92:18	212:11 213:8
149:3	231:13,14,16,21	68:19 72:16 73:18	125:19 251:22	223:20 224:22
PSURs 26:20 70:18	259:13 265:20	73:19 74:4,7	256:12 296:21	244:16 266:25
72:22 73:2,2	296:13	75:16 76:22 82:23	302:23	raises 174:3 176:21
143:5 148:17,19	putting 34:4 206:17	82:25 86:21 91:1	questions 6:10 19:8	274:6
public 1:17 70:25	234:16 258:12	93:11 98:21 99:4	21:5,5,8 52:21	raising 251:25,25
117:20 122:11	p.m 44:2 121:10,12	99:16 101:9	56:7 66:3 81:7	rate 141:15 300:25
132:2,18 133:15	121:12,16 168:12	102:12 104:2	84:11 101:12	301:4,5,12,14
196:1 200:6,22	168:13,14,18	115:2 128:3,9	104:15 106:24	rates 273:9,10,11
202:25 206:3	215:22,23,24	130:6 132:6	120:7 131:18	273:13 301:3
238:3 265:10	216:2 226:6,7,8	134:21 135:17	145:13 174:4	302:10
273:7 286:8	226:12 247:6,10	136:2 137:16	176:21 177:3	ratified 158:17
293:25 297:4	285:18 286:5	139:9 141:1,5	182:3 220:18	ratify 214:6
publication 96:19	306:8,10	142:17 144:2,5	244:16 247:12,18	reached 102:18,23
publications 96:21		145:4 146:12	251:25 252:1	103:9,23 108:6
96:22 109:21	Q	148:14,15 150:1	258:8 266:7	115:6 132:12
publicly 116:16	QSIP 160:20 162:1	152:14,17,21	268:16,17,21	202:25 265:25
published 109:14	180:17	153:8,19 158:25	272:4 296:6	270:8
publishes 112:4	qualified 220:9	161:13 162:20	297:13,14,14,19	reaching 135:22
Pugliese 1:15 4:16	227:23 263:25	165:11,25 166:18	301:12 302:13	137:13 286:7
				[
	× · · · ·			

Videotaped

June 30, 2010

				- Page 330
122.10	240 16 254-16	224.2 262.19	300:17 301:23	reference 103:13
reacting 123:18	249:16 254:16	234:3 262:18	300:17 301.23	105:2,5 117:9
reaction 18:17	263:4 284:10	264:17 265:8,11 265:19 266:1,14	recognizing 181:3	130:23 144:24
166:14 187:8	290:12 295:3	•	recognizing 181.3	148:12 149:18
reactions 86:15	296:1,24	266:20 270:9	111:21 139:2	155:1 165:3
read 12:9,9,13	realtime 1:16 63:7	272:9 273:2,3,4,8	156:1 206:9	181:25 182:17
20:15 22:3 23:24	88:12 92:15	273:9,11,14		183:13,14,14,24
24:3,4 26:16 50:7	288:12 289:5	275:24 276:1	recombine 10:20	186:23 194:3,17
50:15 52:10 71:25	real-life 304:16	287:15	recommendation 95:21	194:18 232:15
72:2 106:24 122:7	reason 7:1 60:2	recalled 86:3 98:15		278:17,18 282:12
122:18 128:24	69:7 74:6 98:15	131:23 136:16	recommendations	referenced 7:16
129:1,4,6,13	108:5 131:24	146:18,22,25,25	112:4,23	93:6 103:12 151:3
130:11,12,12,25	160:1	147:8,10 270:5	recommended	
132:15,19 137:6	reasonable 218:2	272:6	16:23 112:22	165:2 192:12
144:2,3 160:15	218:10 247:24	recalling 19:17	reconcile 235:3	204:10 231:25
166:5,19 167:19	248:4,5,10 251:23	recalls 97:22 98:7,8	reconvening 68:20	references 194:18
189:2 230:15	252:5 253:4 254:3	215:6	record 4:2,5 5:13	204:19
268:11 269:15,25	279:24	receipt 158:10	8:7,22 10:22 50:1	referencing 78:11
271:3 279:15,18	reasons 158:6	204:5 208:15	64:11,14,20 83:12	183:11 230:13
279:20 280:16,18	227:25 298:10	receive 44:15 60:23	104:17,19,21,23	232:3
283:16,17 285:20	rebut 291:8	62:14 72:21,22	121:6,8,14 152:10	referred 24:10
307:5	recall 3:20 13:21	73:1 91:7	168:9,11,16	138:12 152:23
readily 232:4	31:15 42:1,21,23	received 9:5 31:15	193:24 199:2	232:18
reading 50:9 109:5	52:20 57:15 62:14	34:7 36:6 38:22	206:25 215:21	referring 8:7 78:3
130:16 167:1	62:23,25 63:3,11	41:24 42:2 45:17	216:1 226:4,10	78:5 117:11 138:4
ready 8:1,3 152:16	74:8 83:17 85:8	45:21 48:15 64:3	247:5,7,9 285:19	reflect 84:6
152:19 297:1	90:17,20 91:4,13	73:5,13 74:10	303:11,22 305:25	reflects 189:10
real 61:9 180:16	93:23 97:24 98:11	95:20 98:24 99:2	306:4	reframe 216:17
219:14 241:8	98:19 103:1,6,14	107:19 109:7	recorded 114:22	refresh 8:10,20
252:6 260:9	103:21 104:8,10	110:3 118:2	records 69:19 92:6	111:21
301:11	104:11 109:25	121:24 158:12	92:7 120:3,4	refuse 224:14
realize 211:25	115:7,23 116:5	166:13 198:4	301:25	refute 114:23 267:6
226:14,17,20	117:21 132:13,19	207:8,16 208:19	recover 121:23	267:7 299:4
227:14 228:2	134:8 135:21	209:21 240:11	recruit 57:6	301:20
231:14 232:6	139:13 141:16,20	262:9	recruited 57:9	regard 68:12 70:14
292:24	146:17 147:21	receives 88:8	58:19	73:23 97:14,18
realized 295:6	156:7 159:3 162:5	receptive 181:14	recurrence 119:14	102:12 104:15
really 17:18 28:25	195:17 197:1,6,6	recess 64:17 121:11	red 54:25 116:25	108:7,13 137:7,20
69:7 74:12,14	197:15,16,18,19	168:13 215:23	117:11 118:19,22	141:19 143:23
78:5 82:5 119:20	197:21,22,25	226:7	118:25 163:16	144:7 162:14,15
136:17,17 144:19	198:5,14,24	recipient 115:18	redacted 118:1	168:20 171:3
166:4,9 174:23	199:17 202:17	recipients 198:7	270:23	185:21 190:19
175:12 180:3	203:5,6 206:11	recite 159:6,9	redaction 185:8	191:13 193:3
188:22 189:24	214:25 215:8,14	recognize 106:1	redo 183:18	195:3 214:10
192:4 241:13	215:16 216:7,22	181:2 298:20	refer 40:8 124:19	215:6 264:17
242:21 245:23	223:24 224:1,1,4	recognized 299:21	180:21	270:12
		(ALCOHOL)	ME CONTRACTOR OF THE CONTRACTO	and the second section of the second

Videotaped

June 30, 2010

				Page 33
regarding 149:8	126:22 128:9	40:24 60:2 197:21	11:23 49:19 61:12	140:2 141:14
164:18 236:3	135:21 137:19,24	REMS 59:2	62:15 68:9 69:6	192:11 193:15
280:21	137:25 168:22	renal 139:23	69:12 70:4 74:21	194:23 195:5
registered 1:15	210:9 217:7	199:24,25 200:9	74:25 77:8 99:9	232:20 266:1
62:16	reliability 129:23	200:17,18 202:4	100:10 102:24	270:8 273:1 275:4
-	reliance 264:1,16	200:17,18 202:4	103:4 105:1,14	275:8
regular 146:7	relied 137:12 264:7	204:19,22 207:20	106:19 108:12	reporter 1:15,16,16
regulations 169:24 172:1 211:8	282:23 283:20	render 48:17 179:8	100:17 100:12	4:1,16 5:4 6:15
	284:11	217:8,12,13	111:15,18 112:18	111:6 114:23
269:22,24		220:24 221:5	113:1,2,23 114:15	144:3 230:15
regulatory 154:23	rely 237:5 286:15	220.24 221.3	117:9 139:12	285:20
175:23 186:8	relying 167:14		140:9 149:5 152:8	reporters 110:17
190:7,18 284:3	264:12	227:20,21 237:3,7	156:18,19 163:18	111:4
reinserted 67:13	remain 284:2	252:15 253:25	169:18 170:6	reporter's 110:23
reiterated 156:5	remainder 271:14	271:12 274:4		114:11,18,24
206:13	remained 217:20	293:8 302:5	171:16 179:17	l ' '
reiterates 161:11	remaining 151:18	rendered 179:12	180:9 181:3,5,6	reporting 4:17 18:21 73:4 106:21
relate 279:14	remediate 36:19	224:23 247:19	182:22 183:11	
related 151:3,4,4	175:22 249:3	252:18 264:7	184:5 187:17	139:5 141:15,19
186:15 188:7	280:1 281:25	288:4	188:18 189:18	143:6,23 144:7,13
relatedness 110:23	remediated 284:14	rendering 220:1	190:5 191:4,12,17	148:20,23 150:16
110:24 111:7,8,9	remediation 27:9	Rennillo 4:17	193:3,15 195:17	155:2 164:19
275:5	29:7 48:22 53:2	reoccurrence	196:8 199:17	166:14 168:23
relates 92:4	143:4 159:3	107:24	202:3 204:11	171:17 187:8,14
relating 83:4	160:10 161:16,22	reorg 212:20	206:6 208:7 216:6	188:7,9 271:4
152:24	175:5,17 178:14	reorganization	217:5,21 218:4,8	273:9,10,11,13
relationship 201:24	178:17 186:5	212:19	218:9,21,25 219:1	275:8 280:2,22
relatively 123:2	189:25 191:23	repeat 27:8,11,25	219:4,15,15,17	281:1 284:4,8
release 23:22 24:10	192:2 211:19	38:13 62:20 82:9	220:8,25 221:22	288:14 292:7
70:25 71:9 117:19	232:23 248:25	101:8 154:12	222:19,24 223:16	reports 13:2 33:18
122:8,18 135:6	279:25 281:23	161:19 162:3	226:22,24 227:9	34:13 35:4 48:10
196:7,24 198:12	284:5,20 285:22	193:8 246:13	230:9,10,21 231:2	49:13 60:7 63:6,9
200:13 201:18,24	286:18 287:4	276:15 291:6	231:22 233:12	66:12,15 72:19,23
202:4 203:1,9,13	remember 21:13,18	repeated 17:19	236:1,16 239:19	72:23 73:3,8,14
203:16,19,25	38:24 43:2 50:3	repeatedly 18:15	239:20 242:25	75:3,20 76:4
204:11,18 205:1,3	51:19 55:20 65:7	112:3 123:16	243:4 247:20	87:22 89:7,18,22
205:14,24 207:7	99:25 111:25	194:13	250:5,18 251:7	90:20,23 103:6,20
207:15 208:14	126:18 127:7	repeating 218:11	255:18 257:21	107:18 110:2,3,11
209:2,8,15,22	129:16,20 132:22	rephrase 218:1,8	274:8,14 275:1	115:19 134:8
272:9,13 273:6,12	167:17 169:6	240:19	276:11 277:9	135:20 140:15,24
287:20 302:25	199:20 230:22	rephrased 218:8	278:4,6 288:1,2	148:19,20 149:13
released 61:2	remiss 251:25	replaced 290:20	294:8	150:19 154:9
196:24 199:1	removal 196:20	replacing 291:22	reported 29:5	167:20 171:7
releases 16:5 196:1	200:10 269:20	reply 208:20	88:15 105:10	174:19 175:6,11
200:5	remove 269:18	report 3:19 7:20,23	108:21 132:13	175:16 186:24
relevant 41:6	removed 40:10,14	8:1 11:10,13,16	134:8 139:12	193:8 195:7

Videotaped

June 30, 2010

				Page 338
100 07 010 1	220.2	107.15	174.10.010.15	107.7 17 02
198:25 212:1	229:3	retrace 127:15	174:12 219:15	197:7,17,23
215:7 217:1	responded 17:21	retrieval 101:24	255:12 279:5	199:17 201:15
239:12,12 249:3	22:25 52:11	102:8	280:23	202:11,19 203:10
264:8 280:3	responding 123:12	returned 89:16	revision 167:11	203:13 204:1
289:18 297:21	123:19 156:8	102:24 103:25	172:17 173:6	205:18 206:7
represent 4:22 50:4	responds 165:17	revealed 268:3	180:12 218:22	215:18 222:24
representatives	response 67:23	review 9:7 13:20	revisions 294:10	228:3,11 245:4
86:13	89:5 104:2 135:15	16:2 33:15 34:16	revoke 172:23	247:20 249:24
represented 46:20	156:4 157:25	35:7 46:6 55:10	reworded 247:23	250:2,6,23 251:15
representing 15:5	158:8 159:8,9	90:10 93:16 96:2	rewording 248:2	252:10,13,16,18
represents 43:12	161:12 163:3	96:7,12,17,18,19	re-analysis 221:16	255:7 257:1 258:4
46:13	164:18 165:9	97:8,10 99:18	re-data 271:5	258:14 259:7
request 9:11 43:16	169:22 171:10,21	101:16 128:22	re-read 166:5	260:7,10 264:21
43:22 46:1,2,15	171:25 172:7	141:10 163:8	re-review 103:3	264:24 265:2,11
160:24 179:1	182:15 190:19	189:2 200:2	Rice 2:3 5:3 124:5	265:16 269:7
240:11 277:21	193:10 223:22	201:25 208:11	278:7 289:7	271:15 272:14,17
289:12	261:1 278:19	234:11 277:7	302:20	273:17 274:6,20
requested 42:7	279:1,3 280:21	299:15	Richard 2:8 4:21	274:24 275:13,21
43:13 44:4,7	287:17 289:3	reviewed 8:9,15	5:18	276:7,13,16,25
require 87:16	292:13	9:23 16:14,18	riding 255:25	277:8,23 279:7,13
required 20:21	responses 6:14	17:22 33:19 38:24	right 8:17 13:10,14	280:14 281:14
133:24 141:24	26:10 48:11,21	60:8,9 67:7 83:5	14:10,12 17:7	283:14 287:19
158:14 159:2	49:1 156:5 159:7	90:16,19 91:11	19:7 34:22,25	291:7,18 296:19
172:8,12,16,17	159:23 163:19	93:20 94:3 95:2,4	35:22,25 36:10,15	297:1 299:14
173:5,24 219:17	171:7	102:16 103:2	37:10 38:8,24	300:23 301:18
268:8	responsibilities	164:17 181:9	39:7,16 41:17	303:10,12 305:24
requirement 98:17	214:10	218:19,19 233:13	44:5,22 45:22	rigorous 141:10
requirements	responsibility	280:20 293:10	46:2 47:15 48:2	rise 193:2,2
129:25,25 148:24	211:10	reviewer 94:22	50:20,21 53:13,14	risk 3:20 10:8
200:7 284:4	responsive 16:25	120:5 133:23	53:15 61:18 66:8	61:13 70:22
requires 177:8	17:8 19:9 27:24	reviewers 114:14	67:1 68:24 69:16	103:21 117:20
180:11	30:12 32:24	reviewing 133:24	82:22 87:7 91:16	118:8 119:3,5,6
requiring 218:21	restricted 35:11	147:14 182:13	97:9 104:8 108:18	119:19,23,25,25
reread 8:5	71:8,12	188:25 189:12	109:23 113:17	120:1,7,14 122:10
research 123:23	result 63:23 81:11	reviews 56:5 95:6,8	120:4 125:9,13,18	123:3,7,11,15
124:6,24 127:9	121:23 155:2	107:2 164:1 208:1	1	136:5,6,21 175:23
162:22	284:23 285:25	232:11,13 233:3	131:3,5 145:5,10	179:24 181:11
resident 274:22	resultant 73:8	revise 171:15	145:17 147:4	186:8 190:7
resides 111:12	resulted 89:17	172:10 174:12	148:5,12 150:6	195:21 196:2,13
resistance 95:23	153:22 184:7	177:10 180:1	153:5 155:5	196:23,24 200:22
resolution 159:1	resulting 89:5	221:7	160:18 163:25	201:1 203:4 205:3
resources 189:25	results 60:19 64:3	revised 161:10	173:15 176:17	206:2 253:9 258:9
respect 157:25	resume 8:12 97:10	164:20 165:13,19	182:2,17,24 185:8	259:21 260:9
respond 15:22 21:4	retain 36:7	166:2 170:20	189:2,20 192:13	265:20 286:8
21:8 83:11 179:24	retention 30:18	172:19,20 173:4	192:21 194:7	287:22 293:25
	<u> </u>			[
		CANADA		

				Page 33
297:4	satisfactory 164:20	scenario 140:18	128:24 129:4	221:10 224:25
risks 117:24 260:9	165:19 167:10	181:10	security 271:11	229:11 246:17
Robert 106:10	170:21,23 172:20	scheduled 15:9	see 9:21 17:23 25:1	262:22 266:13
robust 27:5,16	176:3 280:23	science 243:9,10	30:15 31:13 44:20	276:2 288:15
Roche 212:18	satisfied 108:22	scientific 253:4	45:15 46:3 49:9	289:6 291:25
213:1	141:18 143:22	254:3 299:21	51:13 53:23 62:4	294:5,6 299:9
role 70:10 80:6	144:6,17 155:19	300:17 301:6,23	68:11 75:4,5 81:7	Segal 1:11 4:11
83:1,6 176:7	155:23 163:3,9	302:2,5	81:12 83:6 85:13	segments 250:21
215:10,11 240:22	165:9,13 166:13	scientifically	86:15 87:9 89:7	selected 48:18
305:3	271:4	301:15	89:16,17 90:6	selection 46:22
rolled 34:16 241:17	satisfy 68:12	scope 15:22,23	96:4 101:17	47:3
rolling 243:25	saw 26:16 91:14	19:19 23:3 29:11	106:20 112:13	self 244:3
root 61:9 161:14	175:4 203:4	34:15 70:20 80:3	115:14 129:9,18	self-confidence
round 26:4 52:16	216:19 232:11	83:19 89:23	130:10 131:15	259:7
244:24 278:8	262:3,8 280:5,7	100:14 136:2,2	135:3 148:4 161:3	selling 260:21
routed 116:8	saying 32:16 34:20	142:7 167:1,2	161:19 163:7	seminars 109:16
routine 60:21 88:6	87:2,3 109:9	203:4 212:14	171:9 173:20	send 22:20 30:9
119:10	112:20 163:2	213:14,16 223:11	182:20 184:24	44:9 46:19 127:2
rule 236:19	167:8 175:24	224:7 234:10	185:11 232:14	146:18 160:21
rules 6:8 239:11	176:20 183:24	244:12 272:16	233:24 248:17,21	161:1 211:21
running 285:2	213:11 230:22	299:14	249:2,15 269:6,10	sending 212:1
	234:5 238:16	screening 120:18	273:22 278:15	seniority 292:23
S	244:18 246:15,18	scribbled 36:21	279:17 280:11	sense 125:22
sad 302:16	258:11 262:20	scrutiny 134:5	304:11	235:23
safe 258:6	271:11 277:3	297:7	seeing 56:22 71:23	sent 3:11 7:8,17
safety 102:7 210:18	288:5,6,15 299:13	se 156:12 266:24	78:11 83:22 295:5	10:4 12:2 16:1
212:19 213:1	says 20:17,19 31:20	search 68:16 124:1	seek 138:10 267:22	22:13,15 23:4,4,8
231:19 249:11	38:9,20 39:9,22	124:1,20 125:8,12	268:8 290:7,9	26:4 30:10 31:21
266:24 298:20,21	39:23 41:20 43:10	125:15,25 126:7	293:18 305:11,14	32:3 38:11,17
300:18 301:24	50:17 78:6 92:20	126:12,19 143:14	305:14	44:16 46:18,23
sake 28:10 70:2	99:24 100:6	175:2 283:16	seeker 80:11 84:2	48:9 53:22 59:11
Sam 112:12	103:23 106:9,20	287:8	261:23,25	68:7 96:2 103:22
sample 61:4 104:5	107:4 108:2	searching 283:13	seeking 245:24	104:5 120:24
301:7	116:24 131:12,19	second 26:4 42:4	seen 7:15 25:24	146:8,9 158:6
sampling 18:21	132:10 140:2	148:10 159:5,11	26:18,19,20,21,23	172:5 188:11
233:16 236:22	142:19 164:16,21	164:17 165:15	26:24 29:9,21	198:14 203:22
252:4 294:9	180:14 182:7	182:5 210:1	51:9 75:2,20,22	207:1 240:14
samplings 66:12	184:1 187:1	269:12 280:18	76:24 77:7,11	244:17,21 249:13
139:16,18	188:22 200:21	secondary 26:16	102:1,2 104:13	262:19 276:21,22
Sarita 38:24 39:23	210:1 263:3	section 91:21,22	108:11 123:7	279:3,5
90:11 206:21	265:21,23 266:3	93:17,18,21,22	131:6 138:21	sentence 50:16
sat 16:20	271:19 273:1	129:7 148:7	163:5 164:3,12	103:23 131:19
satisfaction 158:1	283:19 301:17	223:15 250:22	166:1 176:2	132:7,10,18
174:22	scanned 57:18,21	251:1 282:5,14	187:18 190:21	137:18 153:20
satisfactorily 161:7	scared 259:12	sections 8:20	201:6 209:5,6	166:20 182:5
	€	1	1	

Videotaped

June 30, 2010

				Page 34
210-1 260-4 12	283:21	101:25 102:4,8	179:14 195:1	somewhat 12:22
210:1 269:4,12 279:16,20 281:3	shaking 6:16	117:15 118:18	215:12 227:25	65:10 81:12 123:4
283:24	sheet 13:23 31:13	135:22,23 136:1,4	239:17,19 240:15	211:15
sentences 107:4	40:10	136:7 140:1,6,11	241:1 267:9	soon 273:11
280:16	sheets 40:15,16	140:20 143:16	301:22	SOP 87:16 110:1
	79:22	156:17 170:9	site 82:1 87:12	SOPs 30:16,21
separate 9:13 10:5	79.22 Sherwani 38:25	205:9 234:2	124:2,22 126:12	66:12,13 275:6
10:6 11:11 12:2	39:13	249:11 266:24	126:22 134:18	sorry 14:1 21:17
60:10,12	she'll 28:3	267:3 288:7	135:9 146:10	42:23 76:8 79:13
separated 11:20		298:20,21,22	151:11 186:24,25	84:16 109:1 116:2
sepsis 94:23	shift 171:20	300:18 301:24	251:10 287:21	151:2 176:5
September 165:16	shipped 147:22		sites 151:12,15,15	178:10 183:4,16
166:6 233:10	shock 94:24	signature 57:19	sitting 131:5	203:20 213:17
septic 94:24	Shook 2:16 4:25	signed 57:16	172:24 229:7	203.20 213.17
sequence 161:6	short 10:16 11:4	significant 174:4	290:25	292:17 294:13
203:12	14:13 35:4 79:6	176:21 245:6,7,11		sort 11:18 27:4
sequential 48:9	97:2 168:2,6	256:11 259:8	situation 15:18	28:21,25 48:25
205:12 242:7,23	183:18 215:19	300:23	51:1,5,10 237:18	
sequentially 241:5	282:8 293:8	significantly	246:2 284:11	60:17 138:22
series 87:17 101:24	297:16	273:13	289:5 291:5	154:21 158:24
106:23 171:2,11	shorten 13:6	silence 125:20	303:12 304:17	162:17,23 193:22
208:20 224:23	shorter 9:17 10:1	126:16 127:2	situations 202:18	209:4 222:8 228:3
serious 143:1 156:5	Shorthand 1:16	128:13	six 3:14 276:15	228:18 234:22
160:3 210:18	shortly 44:14	silent 140:15,24	size 115:6 301:7	242:7,13 245:25
261:3,4 287:4	show 105:23 175:1	141:24 142:8	sketched 66:9	249:16 250:15
304:17	185:6 206:1	similar 40:16 75:12	sketching 81:8	272:11,15,16
seriously 130:23	284:12 301:3	78:13 89:22	small 94:23 132:11	274:1 283:18
178:23 260:5	showed 51:21	161:19	151:24 227:17	286:15 290:17
seriousness 172:6	231:19 233:19	simple 24:16 27:6	241:22 265:24	301:13
serve 220:12	246:10 274:12	77:7 82:21 148:14	270:7	sorting 56:12
237:16 294:10	showing 297:3	152:21 172:9	smaller 40:12 42:4	187:21
296:17	shown 19:8 117:19	213:20	44:15 46:14,21	sought 261:5
served 10:14	229:4 235:23	simply 13:15 21:9	196:23	sound 29:2
server 22:16	264:19 275:21,22	54:1,8 56:9 68:15	Smart 3:14 55:9,16	sounds 212:11
124:10,24 125:19	shows 18:25 265:20	73:13,17 188:7	55:17,23 57:3,4	285:1
services 78:19	291:23	204:19 248:15	57:11,23 58:15,24	source 38:22
252:12	sic 166:18 270:10	simultaneously	59:8,13 78:24	sources 26:17,18
set 7:8 9:25 160:15	side 42:13 69:7	187:20	79:8 240:21	South 2:4,13
182:2 192:10	90:5,6,7 92:3,4	Singer 1:12 4:11	245:18,19,19	Southern 1:1 4:9
193:1,13 195:3	234:2,2,7	single 61:13 72:4	solely 187:7 264:12	space 7:10 29:8
199:17 213:25	signal 70:14,19	74:13 87:10	somebody 33:17	34:4 46:7,17,24
301:25	73:24 74:25 82:13	166:19 250:14	56:23 126:11	51:24 52:8 138:1
setting 181:20	83:16 84:6 85:15	single-case 284:8	192:6 240:11	138:14,14,17
293:2	86:1 87:1,5,20	288:14 289:18	301:20	147:19 159:15
settle 300:7	90:5,23 91:21	sit 19:13 69:1 79:18	someplace 219:20	164:10 174:12
seven 282:19,19	92:4 93:17,22	84:10 85:1 179:10	1 -	217:20 246:23
SCYCH AOA, LZ, LZ	1 74.4 70.11,44	1 01110 0011 177110	1	1

Videotaped

June 30, 2010

				Page 341
spaces 105:20	spheres 71:12	120:7 129:17,21	145:7 178:5 192:3	289:22
spaces 105:20 159:15 161:25	spidering 211:12	129:22 160:7,9	192:6 217:22	stricken 145:9
244:21	spite 84:10	173:24 219:10	223:17 248:2	strike 32:25 86:6
speak 6:18,19	split 9:12 250:7,13	228:12 258:21	251:10 259:14	90:2 93:14,19
55:15,19 142:9	282:8	261:24 266:7	262:5 268:2,11	153:25 185:20
•	spoke 19:16 24:23	272:7 301:12	293:11 296:10	297:24
speaking 146:25	78:24 84:7 234:23	305:4	states 1:1 4:9 109:3	strong 211:23
speaks 99:22 265:7	spoken 122:4	starting 120:13	148:16 149:2	259:22 260:4
spec 60:19 specific 15:18 17:9	153:18 300:20	150:12 282:18	214:1 272:20	stronger 290:21
17:20,25 18:1,10	spot 140:20	288:19	state-level 127:20	292:9 294:5
	spots 58:24	starts 50:8 129:12	243:25	strongly 141:18
18:11,14,16 19:3 19:5 22:21 23:24		150:3 210:23	stating 117:20	struck 17:18
	spreadsheet 27:6	state 5:12 18:13	stating 117.20	structurally 213:25
51:4,20 52:5,19	stack 31:5 37:3,10 42:19 45:25 60:5	57:1 181:17	118:15	study 202:14
53:7 83:15 92:12		189:21 223:2	status 168:22	stuff 225:9 246:11
100:13 102:12,20	275:15,17 277:12	241:16	status 108.22 stay 16:9 23:2	subdivided 21:6
103:2 105:25	stacked 42:14	stated 171:16 182:9	37:21,21 46:10	249:1
110:4 113:10	stake 226:15 228:2	185:13 189:13	174:7	subject 98:18 275:8
160:2 193:17	239:11 261:15		stayed 258:24	289:2
195:2 268:2	stamped 172:4	282:7	299:25	subjected 95:25
288:25	stand 64:9 111:23	statement 11:4 16:21 24:22 102:4	staying 19:18	subjecting 259:20
specifically 18:19	147:15 163:10		staying 19.16 step 253:16	subjecting 239.20 subjects 15:16
19:18 30:6 32:9	190:5 221:11	114:10 122:10,13		submission 11:21
42:14 46:16 51:16	227:24 228:5,20	123:1 124:12	steps 127:15	178:15 186:25
54:11 62:25 63:16	229:9,11,16,20	131:25 132:18,24	step-wise 34:12 stick 15:21 293:14	187:2 189:1 212:5
117:14 125:20	238:25 251:16	133:3,4 134:7	sticker 44:23 45:7	275:9 278:4
129:20 150:21	253:24 254:6	137:5,10,24	58:5	submissions 191:24
178:20 195:19	256:4,6 258:13	141:11 142:1	stickers 44:20	submit 51:14
199:23 203:2	259:22 266:16	143:1,22 144:6,14		113:13,21,22
223:5 231:6 251:9	281:20 302:23	144:18 149:20	stimulated 141:16	148:17 149:3
299:25	standard 123:10	161:20 165:18	stipulated 98:22	239:5
specification 115:7	202:16 275:11	175:8,18 184:23	stipulations 4:2	1
specifications	287:14	184:25 186:9	stockpiling 212:1	submitted 11:7,21
115:15	standing 238:1	217:24 224:8	stood 111:20	59:21 76:1,4
specifics 21:18	271:11	265:1,4,10 266:14	stop 23:12 47:12	88:21,23 107:5,8
52:20 104:8 172:2	start 41:13 64:21	266:17 267:6,12	75:14 130:5	120:18 161:25
189:19 223:24	66:17 81:23 82:6	267:24 268:11	185:19 212:10	174:21 175:16
230:12 284:7	85:17 121:15	287:2 289:21	256:23 303:21	176:1 178:16
specify 82:1	168:17 220:10,13	290:17 291:23	stopped 240:25	182:10 186:6
speculate 196:19	226:11 286:4	292:5 293:13	stopping 34:13	187:11 189:10
speculative 223:4	292:25	298:23 299:5	stops 202:12	222:23 226:23
speed 96:4	started 10:6 15:14	304:4,10	stories 111:2	276:23
spend 94:14	15:23 33:15,19	statements 12:20	stray 37:6 140:1	submitting 10:20
spent 78:21 94:19	34:4,8 46:5 47:7	24:21 29:2 92:12	Street 1:12 2:13	143:2 175:11
187:20 219:7	48:25 65:14,17,23	101:19 104:10	4:12	250:9
234:13	84:1 85:11 96:3	132:2,4 133:16	strength 238:24	suboptimal 224:13
1		***		

Videotaped

June 30, 2010

sufficient 227:20 supposed 181:5 160:5,13 161:15 64:7 75:11 79:23 124:12 127:17 229:14,15 238:10 186:4 205:8 249:10 79:24 98:3 100:9 129:22 145:16 290:13 suprapotency 119:9 18:19 19:3,4 112:25 144:12 171:21 175:10 141:18 supratherapeutic 70:17 80:22 82:2 150:3 168:2,3,6,7 183:12 185:19 suggesting 67:16 274:2 83:16 100:13 177:10 179:25 186:9 187:9,10,11 205:22 sure 9:15 20:10,20 162:2,21 212:15 193:22 206:11 296:3 300:13 suitable 218:22 81:4 112:20 20:24 41:14 42:25 212:16 213:15 207:24 213:6 296:3 300:13 suitable 218:22 81:4 112:20 240:12 284:2 236:17 261:1 204:21 summaries 152:13 168:8 175:18 28:7 292:6 272:15 204:21 summarize 31:23 168:8 175:18 192:21 199:4 5-C-I-O-M-S 112:8 64:7 66:7 67:12 121:9,15 168:17 32:2 33:10 192:21 199:4 7 7 7 7 7 7 7 7 7 <th></th> <th></th> <th>·</th> <th></th> <th>Page 342</th>			·		Page 342	
Subsequent 19:9 supervision 22:1 supervision 23:1 supervis	225,10.21	supersode 166.8	283-4 202-13	74.23 75.6 77.13	takes 112·16	
subsequent 26:3 supervisors 16:18 supervisors 95:19 supplement 11:10 suprised 236:22 surpoinding 102:23,24 103:23 41:14 talk 33:16 84:8 subsequently 204:4 subset 18:2,18 subsets 16:06 subset 18:2,18 subsets 16:06 substance 14:11 38:3 65:1 198:11 199:20 substance 14:11 205:7 231:23 supplement 11:10 205:7 231:23 swayed 230:24 swaye 19:13 swayed 230:24 psi-13	•	_				
Supervisory 95:19 Supervisory 95:19 Supprised 236:22 Subsequently 204-4 Subset 18:2,18 262:3 289:24 Substantial 11:12,18,24 125:14 115:6 117:6,17,18 133:17 178:11 198:11 199:20 205:7 231:23 238:11 248:19 205:7 231:23 238:11 248:19 256:17 261:12,16 262:24 295:20 248:20 291:24 256:17 261:12,16 248:20 291:24 248:20 291:24 248:20 291:24 248:20 291:24 256:23 24:19 276:12 298:22 276:12 299:22 276:12 299:22 276:12 299:22 276:12 299:22 276:12 299:22 276:12 299:22 276:12 299:22 276:12 299:22 276:12 299:22 276:12 299:22 276:12 299:22 276:12 299:22 276:12 299:22 276:12 299:22 276:12 299:22 276:12 299:22 276:12 299:22 276:12 299:22 276:12 299:22 27	~ .		_+ ···-		l '	
subsequently 204-4; subset 18:2,18 supplement 11:10 11:12,18,24 supplemental 12:11 11:12,18,24 supplemental 12:12,13 125:14 102:23,24 103:23 85:18 129:17 14:24:145:18 125:14 103:24,24 107:18 14:24:145:18 14:24:145:18 120:12,23 23,24 103:23 85:18 129:17 14:24:145:18 125:14 103:24,24 107:18 11:24:44:15:18 120:11 25:14 14:24:145:18 120:11 25:16 11:12,13,24 supplemental support 12:10 28:11 248:19 249:14,21,22 sweden 88:22 tablets 103:9,17 104:11 107:19 11:12,11 25:16 11:12,17 12:11 25:16 12:11 25:16 103:23 11:298:22 28:24 299:23 29:23 11:123:123 29:23 11:123:12 swy 29:5 Swy 29:23 125:14 120:82:17:26:24 120:82:27:17:26:24 120:82:23:15:5 120:82:23:15:5 <th colsp<="" td=""><td>-</td><td></td><td>-</td><td></td><td></td></th>	<td>-</td> <td></td> <td>-</td> <td></td> <td></td>	-		-		
Subset 18:2,18 26:23 289:24 supplemental 23:318 supplemental 23:32 supplemental 23:318 supplemental 23:311 substantial 23:318 supplemental 23:311 substantial 23:318 supplemental 23:32 supplemental 23:323 supportive 23:323 suppor	•				l e e e e e e e e e e e e e e e e e e e	
Substat 160:6			_			
Substance 14:11 205:7 231:23 swapport 122:10 238:11 248:19 238:11 238:19 238:11 248:19 238:11 238:19 238:11 238:19 238:11 238:19 238:11 238:19 238:11 238:10 238:11 238:10 238:11 238:10 238:11 238:10 238:11 238:10 238:11 238:10 238:11 238:10 238:11 238:10 238:11 238:10 238:11 238:10 238:11 238:10 238:11 238:10 238:11 238:10 238:11 238:10 238:11 238:10 238:11 238:10 238:11 238:11 238:11 238:11 238:11 238:11 238:11 238:11 238:11 238:11 238:11 238:11 238:11 233:11 238:11 233:11 238:11 233:11 238:11 233:11 238:11 233:11 238:11 238:11 233:11 238:11 233:11 238:11 238:11 233:11 238:11 238:11 238:11 233:11 238:11 233:11 238:11 233:11 238:11 238:11 238:11 233:11 238:11 238:11 238:11 238:11 238:11 238:11 238:11 238:11 238:11 238:11 238:11 238:11 238:11 238:11 238:11 238:11 233:11 238:11 238:11 238:11 233:11 238:11 238:11 238:11 238:11 233:11 238:11 238:11 238:11 233:11 238:11			· ·	•		
substance 14:11 support 122:10 sway 229:5 120:8 273:21 talked 15:21 19:18 198:11 199:20 238:11 248:19 249:14,21,22 249:24 276:12 298:22 299:23 79:885:25 91:11 substantially 251:20 249:14,21,22 256:17 261:12,16 262:24 295:20 28weden 88:22 talkets 103:9,17 104:11 107:19 127:11 143:7 substantiate substantiate 19:23 133:11 supported 196:20 supported 196:20 swptomase 16:03 18:3,5 119:23 159:14 169:23 49:4 59:11 34:9,10,17 35:8 49:4 59:11 10:17 11:18 71:13 5ystem 10:7 26:24 170:10 267:3 298:25,8,16 299:1 211:4 21:14 199:17 200:9,10 success 244:14 success 244:14 supportive 254:19 256:23 256:23 286:18 299:20 302:7 2298:5,8,16 299:1 233:23 177:14 191:9 217:12 20:12 233:23 177:14 191:9 217:12 20:21 211:14 21:14 211:14 21:14 217:11 120:22 127:11 143:7 177:14 191:9 217:12 6:24 127:11 143:7 177:14 191:9 217:12 6:24 127:11 143:7 127:11 12:6 127:11 12:17 131:22 13:21 29:11 12:			-	1		
38.3 65:1 198:11 198:11 199:20 205:7 231:23 substantial 82:18 substantial8 21:8 substantial8 21:8 substantial8 21:0 256:17 261:12,16 251:20 substantive 21:10 34:9,10,17 35:8 49:4 59:11 success 244:14 success 244:15 success 244:16 success 244:16 success 244:17 success 244:17 success 244:18 success 244:19 255:23 supports 245:9 265:23 supports 245:9 sufficient 227:20 sufficient 227:20 suggest 89:8 141:17 141:18 suggest 89:8 141:			_	•		
198:11 199:20 238:11 248:19 249:14,21,22 249:14,21,22 249:12,251:20 262:24 295:20 248:20 291:24 249:20 248:20 291:24 249:4 59:11 249:4 59:11 249:4 59:11 249:4 59:11 249:4 59:11 249:4 59:11 249:4 59:11 249:4 59:11 249:4 59:11 249:4 59:11 249:4 59:11 249:4 59:11 249:4 59:11 249:4 59:11 249:4 59:11 249:4 59:11 249:4 59:11 249:4 59:11 249:23 133:11 249:24 25:20 249:20		* *				
substantial 82:18 substantially 251:20 249:14,21,22 constraints Sweden 88:22 substantially 256:27 261:12,16 262:24 295:20 tables 103:9,17 104:11 107:19 116:17,25 117:9 116:17,25 117:9 23 120:12,19 121:24 symptoms 274:1,12 symp						
Substantially 256:17 261:12,16 262:24 295:20 substantiate 262:24 295:20 substantiate 248:20 291:24 supported 196:20 248:20 291:24 supporting 10:12 34:9,10,17 35:8 49:4 59:11 71:17,19 75:24 5uccess 244:14 success fully 239:3 295:24 supportise 254:19 256:23 supports 245:9 262:2 supports 245:9 262:2 supports 245:9 292:14,15 238:10 290:13 suggest 89:8 141:17 141:18 suggest 89:8 141:17 141:18 suggest 691:5 suggest on 16:2 surpatherapeutic 205:22 surpatherapeutic 205:24 33:21 256:41 38:21 256:41 38:21 256:41 38:31 23:21 33:10 summarized 233:11 summarized 233:11 summarized 233:11 summary 48:13 section 24:17 169:21 170:3 def:17 248:12 46:17 248:13 46:10 248:22 26:17 248:12 26:17						
251:20 substantiate 119:23 133:11 349:10,17 35:8 49:4 59:11 349:10,17 35:8 49:4 59:11 349:23 133:11 320:248:20 291:24 526:23 520:24 295:20 524:14 520:291:24 526:23 520:24 295:24 526:23 520:24 295:24 526:23 520:24 295:24 526:23 520:24 295:24 526:23 520:24 295:24 526:23 520:24 295:24 526:23 520:24 295:24 526:23 520:24 295:24 526:23 520:24 296:19 270:7 526:18 526:24 526:23 528:49:10 529:14,15 238:10 529:13 520:22 520:24 520:22 520:24 520:22 520:23 520:24 520:24 520:24 520:24 520:24 520:24 520:24 520:24 520:24 520:25 520:26 520:26 520:26 520:26 520:27 520:27 520:27 520:28 520:28 520:29:14,15 238:10 520:29:14,15 238:10 520:29:14,15 238:10 520:29:14,15 238:10 520:29:14,15 238:10 520:29:14,15 238:10 520:29:14,15 238:10 520:22 520:24 520:22 520:24 520:22 520:24 520:22 520:24 520:22 520:24 520:22 520:24 520:22 520:22 520:24 520:22 5			*	l '	l ·	
substantiate supported 196:20 symptomatic 160:3 symptoms 274:1,12 118:3,5 119:23 159:14 169:23 177:14 191:9 159:14 169:23 177:14 191:9 159:14 169:23 177:14 191:9 159:14 169:23 177:14 191:9 159:14 169:23 177:14 191:9 159:14 169:23 177:14 191:9 177:17 10:10 267:3 299:20 302:7 299:20 302:7 211:14 220:21 233:23 181:9 19:3 181:9 16:16 186:61 57:20 299:20 302:7 299:20 302:7 299:20 302:7 299:20 302:7 299:20 302:7 200:13 186:41 66:61 57:20 40:13 51:18 61:16 40:13 51:18 61:16 40:13 51:18 61:16 40:13 51:18 61:16 40:13 51:18 61:16 40:13 51:18 61:16 40:13 51:18 61:16 40:13 51:18 61:16 40:13 51:18 61:16 40:13 51:18 61:16 40:13 51:18 61:16 40:13 51:18 61:16 40:13 51:18 61:16	•	•				
248:20 291:24 supporting 10:12 synthesize 112:17 system 10:7 26:24 269:19 270:7 270:17 120:9,10 211:14 212:14 200:19,10 211:14 212:14 200:19,10 211:14 212:14 211:14 200:19,10 211:14 212:14 211:14 211:14 211:14 211:14 200:19,10 211:14 212:14 211:14				l '	l '	
substantive 21:10 supporting 10:12 supporting 10:12 10:17 11:18 71:13 17:17,19 75:24 10:17 11:18 71:13 70:17 11:18 71:13 77:17,19 75:24 10:17 11:18 71:13 synthesize 112:17 13:22 132:12 192:17 200:9;10 21:14 212:14 21:12 21:17 19:17 200:9;10 21:14 212:14 220:11:4 212:14 220:12:12 192:17 200:9;10 21:14 212:14 220:11:4 212:14 220:11:4 212:14 220:11:4 212:14 220:11:4 212:14 220:11:4 212:14 220:11:4 212:14 220:11:4 212:14 220:11:4 212:14 220:11:12 20:12 231:23 192:17 200:9;10 211:14 212:14 221:14 21:14 21:21 192:11 22:12 192:11 22:12 192:11 22:12 192:17 200:9;10 211:14 21:21:14 21:11:12 23:12:12 192:11 22:13 192:11 22:12 192:11 22:12 123:12 192:17 200:9;10 123:12		11		·	1 '	
34:9,10,17 35:8 49:4 59:11 success 244:14 successfully 239:3 295:24 suck 282:25 suddenly 227:9 sufficient 227:20 229:14,15 238:10 290:13 suggest 89:8 141:17 141:18 suggest 89:8 141:17 141:18 suggesting 67:16 205:22 suggestion 16:2 suggestion 16:2 suggestion 16:2 suggestion 16:2 suggest 89:15 suggest 91:5 suggest 91:5 suggest 91:5 suggest 91:5 suggest 92:3 supportive 254:19 205:22 supportive 254:19 205:22 supposed 181:5 suggest 89:8 141:17 141:18 suggest 89:8 141:17 141:18 suggest 89:8 141:17 141:18 suggest 91:5 suggest 91:5 suggest 91:5 suggest 89:8 141:17 141:18 suggest 89:8 14:17 141:18 suggest 89:8 14:14 110:15;13 106:24 110:15;13 106:24 110:15;13 106:24 110:15;13 106:24 110:15;13 106:24 110:15;13 106:24 110:15;13 106:24 110:15;13 106:24 110:15;13 106:24 110:15;13				•	The state of the s	
49:4 59:11 success 244:14 successfully 239:3 295:24 supportive 254:19 256:23 29siddenly 227:9 sufficient 227:20 299:14,15 238:10 299:13 suggest 89:8 141:17 141:18 suggesting 67:16 205:22 suggesting 67:16 205:22 suggesting 243:16 205:24 suggesting 243:16 205:24 suggesting 67:16 205:22 suggesting 243:16 suggesting 243:16 suggesting 243:16 summarize 31:23 32:2 33:10 summarized 233:11 summarized 233:11 summarized 233:11 summarized 233:11 summarized 233:11 summarized 233:13 supportive 254:19 256:23 281:1,13 284:2 286:18 170:10 267:3 288:11,13 284:2 170:10 267:3 288:18,13 299:20 302:7 tactfully 56:8 take 6:16 7:1 10:12 166:15 77:20 14:16 32:9,12 12:17:11 220:21 233:23 14lking 18:12 23:23 12:12 33:23 1299:20 302:7 14:16 32:9,12 1299:20 302:7 14:16 32:9,12 14:16 32:9,12 129:24 98:3 100:9 129:22 145:16 64:7 75:11 79:23 129:22 245:16 15:6: 157:20 129:14:16 32:9,12 129:24 98:3 100:9 129:22 145:16 64:7 75:11 79:23 129:22 206:11 120:21 177:10 179:25 186:4 170:10 267:3 288:18 14 16:12 3:23 129:22 82:2 15:6: 157:20 14:16 32:9,12 129:24 98:3 100:9 129:22 145:16 64:7 75:11 79:23 129:22 145:16 110:15 120:22 14:12 120:21 1						
success 244:14 successfully 239:3 295:24 supportive 254:19 256:23 supports 245:9 262:2 supports 245:9 262:2 supposed 181:5 186:4 suprapotency 299:13 suggest 89:8 141:17 141:18 suggesting 67:16 205:22 205:24 suggesting 67:16 205:22 suggesting 67:16 205:22 suggesting 16:2 suggesting 243:16 suggesting 243:16 summarize 31:23 32:2 33:10 summarized 233:13 supportive 254:19 256:23 supports 245:9 262:2 supposed 181:5 160:5,13 161:15 205:8 249:10 18:19 19:3,4 117:10 179:23 112:25 144:12 119:9 supratherapeutic 139:22 273:20,24 274:2 117:11 179:25 117:10 179:25 118:11 17:10 179:25 117:10 179:25 118:11 17:10 179:25 118:11 17:10 179:25 118:11 17:10 179:25 118:11 17:10 179:25 118:11 17:12 175:10 118:11 17:12 175:10 118:11 17:12 175:10 118:11 17:12 175:10 118:11 17:12 175:10 118:11 17:12 175:10 118:11 17:12 175:10 118:11 17:12 175:10 118:11 17:12 175:10 118:11 17:12 175:10 118:11 17:12 175:10 118:11 17:12 175:10 119:9 117:11 17:12 175:10 119:9 117:11 17:12 175:10 119:9 117:11 17:12 175:10 119:9 117:11 17:12 175:10 119:9 117:11 17:12 175:10 119:9 117:11 17:12 175:10 119:9 117:10 179:25 110:13 117:11 17:12 175:10 118:19 19:3,4 117:10 179:25 119:22 179:14 117:11 17:25 118:11 18:13 17:23 117:11 17:15 123:6,9 117:10 179:25 118:11 18:13 18:12 23:23 117:11 17:12 175:10 119:9 119:24 98:3 100:9 119:20 119:9 1						
successfully 239:3 supportive 254:19 281:1,13 284:2 299:20 302:7 talking 18:12 23:23 295:24 suck 282:25 supports 245:9 286:18 systemic 139:16 14:16 32:9,12 40:13 51:18 61:16 61:19 76:3 78:2 85:7 96:22 109:20 85:7 96:22 109:20 129:11 70:3 14:16 32:9,12 40:13 51:18 61:16 61:19 76:3 78:2 85:7 96:22 109:20 129:12 17:17 14:16 32:9,12 14:16 32:9,12 14:16 32:9,12 14:16 32:9,12 14:16 32:9,12 14:16 32:9,12 14:16 32:9,12 14:12 32:23 40:13 51:18 61:16 61:19 76:3 78:2 85:7 96:22 109:20 129:22 145:16 61:19 76:3 78:2 85:7 96:22 109:20 129:12 17:11 129:12 17:12 129:12 17:12 129:12 17:12 129:12 17:12 129:12 17:12 129:12 17:12 129:12 17:12 129:12 17:12 129:12 17:12 129:12 17:12	i I	•	·			
295:24				·		
suck 282:25 supports 245:9 systemic 139:16 take 6:16 7:1 10:12 61:19 76:3 78:2 suddenly 227:9 sufficient 227:20 supposed 181:5 156:6 157:20 160:5,13 161:15 205:8 249:10 79:24 98:3 100:9 124:12 127:17 290:13 suprapotency systems 3:20 18:1 10:5,13 106:24 10:5,13 106:24 146:24 170:2,2 suggest 89:8 141:17 119:9 70:17 80:22 82:2 83:16 100:13 177:10 179:25 183:12 185:19 suggesting 67:16 205:22 sure 9:15 20:10,20 83:16 100:13 177:10 179:25 188:10,14 212:15 205:22 sure 9:15 20:10,20 162:2,21 212:15 193:22 206:11 296:3 300:13 suing 243:16 68:7 69:2,13,13 219:12 223:13 207:24 213:6 206:3 168:2,3,6,7 188:10,14 212:15 suitable 218:22 81:4 112:20 20:24 41:14 42:25 212:16 213:15 207:24 213:6 20:24 20:10 236:17 26:11 226:3 300:13 summarize 31:23 168:8 175:18 175:18 5-C-I-O-M-S 112:8 46:17 66:7 67:12 20:24:21 140:16 149:17 226:25,311 285:3 summarized 22			•			
suddenly 227:9 262:2 156:6 157:20 14:16 32:9,12 85:7 96:22 109:20 suddenly 227:9 262:2 156:6 157:20 14:16 32:9,12 85:7 96:22 109:20 229:14,15 238:10 290:13 suprapotency 156:6 157:20 14:16 32:9,12 46:7 5:11 79:23 124:12 127:17 290:13 suprapotency 19:9 18:19 19:3,4 10:5,3 106:24 11:25 144:12 17:10 179:25 146:24 170:2,2 177:10 179:25 146:24 170:2,2 177:10 179:25 186:9 187:9,10,11 18:19 19:3,4 70:17 80:22 82:2 150:3 168:2,3,6,7 186:9 187:9,10,11 18:19 19:3,4 177:10 179:25 186:9 187:9,10,11 18:14:12 20:10 180:1 189:5 186:9 187:9,10,11 188:10,14 212:15 296:3 300:13 303:21 18:14 112:20 248:7 224:12 23:13 228:7 225:14 <td></td> <td>— -</td> <td></td> <td>1</td> <td>*</td>		— -		1	*	
sufficient 227:20 supposed 181:5 160:5,13 161:15 64:7 75:11 79:23 124:12 127:17 299:13 suprapotency 119:9 119:9 18:19 19:3,4 112:25 144:12 171:21 175:10 141:18 supratherapeutic 139:22 273:20,24 83:16 100:13 177:10 179:25 186:9 187:9,10,11 205:22 sure 9:15 20:10,20 162:2,21 212:15 193:22 206:11 206:2,21 212:15 suing 243:16 68:7 69:2,13,13 219:12 223:13 215:18 220:10 206:3 300:13 suitable 218:22 81:4 112:20 228:7 292:6 272:15 206:17 261:1 207:24 213:12 summarize 31:23 192:21 199:4 223:11 225:7 228:9 236:8,9 243:7 244:22 233:10 223:11 225:7 228:9 236:8,9 243:7 244:22 43:12 45:13 46:22 226:7 283:25 184:11 186:8 194:24 215:23 226:7 283:25 226:7 283:25 226:7 283:25 226:7 283:25 226:7 283:25 226:7 283:25 226:7 283:25 226:7 283:25 226:7 283:25 226:7 283:25 226:7 283:25 226:7 283:25 226:7 11:10 226:7 283:25 226:7 283:25 226:7 283:25 22			, •			
229:14,15 238:10 290:13 suggest 89:8 141:17 141:18 suggesting 67:16 205:22 suggestion 16:2 suitable 218:22 Suite 1:12 summarized 233:11 summarized 233:11 summary 48:13 86:17 96:9 169:17 169:23 229:14,15 238:10 205:8 249:10 39ystems 3:20 18:1 101:5,13 106:24 110:5,13 106:24 112:25 144:12 117:21 175:10 188:10 10:3,4 112:25 144:12 117:20 179:25 188:16 100:13 177:10 179:25 188:10,14 212:15 296:3 300:13 303:21 188:10,14 212:15 296:3 300:13 303:21 188:10,14 212:15 296:3 300:13 303:21 188:10,14 212:15 296:3 300:13 303:21 188:10,14 212:15 296:3 300:13 303:21 188:10,14 212:15 296:3 300:13 303:21 188:10,14 212:15 296:3 300:13 303:21 188:10,14 212:15 296:3 300:13 303:21 188:10,14 212:15 296:3 300:13 303:21 188:10,14 212:15 188:10,14 212:15 296:3 300:13 303:21 188:10,14 212:15 296:3 300:13 303:21 188:10,14 212:15 296:3 300:13 303:21 188:10,14 212:15 188:10,14 212:15 188:10,14 212:15 296:3 300:13 303:21 188:10,14 212:15 188:10,14 212:15 188:10,14 212:15 188:10,14 212:15 188:10,14 212:15 188:10,14 212:15 188:10,14 212:15 188:10,14 212:15 188:10,14 212:15 188:10,14 212:15 188:10,14 212:15 188:10,14 212:15 188:10,14 212:15 188:10,14 212:15 188:10,14 212:15 188:10,	suddenly 227:9			•		
290:13 suggest 89:8 141:17 141:18 suggesting 67:16 205:22 suggestion 16:2 suitable 218:22 Suite 1:12 summarize 31:23 32:2 33:10 summarized 233:11 summary 48:13 86:17 96:9 169:17 169:21 170:3 suggest 89:8 141:17 129:9 supratherapeutic 119:9 supratherapeutic 119:9 supratherapeutic 18:19 19:3,4 70:17 80:22 82:2 150:3 168:2,3,6,7 183:12 185:19 180:1 189:5 180:1 18:19 18:19 19:4 18:19 19:4,4 12:25 144:12 171:21 175:10 183:12 185:19 180:1 18:19 18:19 19:4,4 12:25 144:12 171:21 175:10 183:12 18:19 18:19 19:4,4 12:25 144:12 171:21 175:10 18:19 19:4,2 171:21 175:10 18:19 19:4,2 171:21 175:10 18:19 19:4,2 171:21 175:10 18:19 19:4,2 171:21 175:10 18:19 19:4,2 17:10 179:25 180:1 18:1 19:4,2 17:10 179:25 186:9 187:9,10,11 18:19 19:4,2 199:22 206:11 180:1 18:1 19:22 199:22 206:11 180:1 18:1 19:22 180:1 18:1 19:22 180:1 18:1 19:22 180:1 18:1 19:22 180:1 18:1 19:22 180:1 18:1 19:22 180:1 18:1 19:2	sufficient 227:20		·	<u> </u>	1	
suggest 89:8 141:17 141:18 119:9 18:19 19:3,4 112:25 144:12 171:21 175:10 18:uggesting 67:16 139:22 273:20,24 83:16 100:13 177:10 179:25 186:9 187:9,10,11 205:22 177:10 179:25 186:9 187:9,10,11 188:19 19:3,4 177:10 179:25 186:9 187:9,10,11 205:22 177:10 179:25 186:9 187:9,10,11 188:10,14 212:15 188:10,14 212:15 205:22 20:24 41:14 42:25 162:2,21 212:15 193:22 206:11 296:3 300:13 303:21 219:12 223:13 215:18 220:10 206:3 10:13 207:24 213:6 206:11 296:3 300:13 303:21 215:24 134:21 288:7 292:6 272:15 204:21 204:21 204:21 204:21 204:21 204:21 204:21 204:21 204:21 204:21 204:21 204:21 204:21 204:21 204:21 204:21 121:9,15 168:17 204:21 121:9,15 168:17 204:21 121:9,15 168:17 226:2,5,11 285:3 285:14,17 286:4 306:5 285:14,17 286:4 306:5 243:7 244:22 243:7 244:22	229:14,15 238:10					
suggested 91:5 supratherapeutic 70:17 80:22 82:2 150:3 168:2,3,6,7 183:12 185:19 suggesting 67:16 139:22 273:20,24 83:16 100:13 177:10 179:25 186:9 187:9,10,11 205:22 sure 9:15 20:10,20 162:2,21 212:15 180:1 189:5 188:10,14 212:15 suggestion 16:2 sure 9:15 20:10,20 162:2,21 212:15 193:22 206:11 296:3 300:13 suitable 218:22 81:4 112:20 240:12 284:2 236:17 261:1 207:24 213:6 206:3 300:13 summaries 152:13 125:24 134:21 288:7 292:6 272:15 204:12 284:2 204:11 4:7 5:19 64:17 66:7 67:12 99:12 121:11 121:9,15 168:17 121:9,15 168:17 226:2,5,11 285:3 285:14,17 286:4 306:5 128:11 186:19 128:11 186:19 129:	290:13			·		
suggested 91:5 suggesting 67:16 139:22 273:20,24 83:16 100:13 177:10 179:25 186:9 187:9,10,11 205:22 sure 9:15 20:10,20 162:2,21 212:15 193:22 206:11 296:3 300:13 suggestion 16:2 20:24 41:14 42:25 212:16 213:15 207:24 213:6 296:3 300:13 suitable 218:22 81:4 112:20 240:12 284:2 236:17 261:1 204:21 summaries 152:13 142:1 150:10 S-C 112:10 127:15 121:14 summarize 31:23 168:8 175:18 S-C-I-O-M-S 112:8 64:17 66:7 67:12 121:9,15 168:17 32:2 33:10 192:21 199:4 207:24 213:12 99:12 121:11 121:9,15 168:17 233:11 223:11 225:7 139:19 40:5,18 186:9 187:9,10,11 188:10,14 212:15 188:10,14 212:15 296:3 300:13 303:21 111 171:25 188:10,14 212:15 207:24 213:6 215:18 220:10 236:17 261:1 204:21 188:10,14 212:15 236:17 261:1 204:21 204:21 222:15 122:15 188:10,14 212:15 236:17 261:1 226:2,511 226:2,5,11 226:2,5,11 226:2,5,11 226:2,5,11 226:2,	suggest 89:8 141:17		·			
Suggesting 67:16 205:22 274:2 117:15 123:6,9 180:1 189:5 296:3 300:13 suggestion 16:2 20:24 41:14 42:25 212:16 213:15 207:24 213:6 296:3 300:13 suing 243:16 68:7 69:2,13,13 219:12 223:13 215:18 220:10 236:17 261:1 204:21 suitable 218:22 81:4 112:20 240:12 284:2 236:17 261:1 204:21 summaries 152:13 142:1 150:10 S-C 112:10 5-C 112:10 5-C 112:10 5-C 112:11 5-C 112:11 121:9,15 168:17 121:9,15 168:17 122:9,15 168:17	141:18			1 ' ' '		
suggestion 16:2 sure 9:15 20:10,20 162:2,21 212:15 207:24 213:6 296:3 300:13 suing 243:16 suitable 218:22 81:4 112:20 242:1 150:10 242:1 150:10 243:12 242:1 150:10 243:14 242:1 150:10 243:12 240:12 284:2 236:17 261:1 296:3 300:13 303:21 296:3 300:13 303:21 296:3 300:13 303:21 296:3 300:13 303:21 296:3 300:13 303:21 296:3 300:13 303:21 296:3 300:13 303:21 296:3 300:13 303:21 296:3 300:13 303:21 296:3 300:13 303:21 296:3 300:13 303:21 296:3 300:13 303:21 296:3 300:13 303:21 296:3 30:21 </td <td>suggested 91:5</td> <td>1</td> <td></td> <td></td> <td>1 ' ' '</td>	suggested 91:5	1			1 ' ' '	
suggestion 16:2 20:24 41:14 42:25 212:16 213:15 207:24 213:6 303:21 suing 243:16 68:7 69:2,13,13 219:12 223:13 215:18 220:10 204:21 <t< td=""><td>suggesting 67:16</td><td></td><td></td><td>}</td><td>1</td></t<>	suggesting 67:16			}	1	
suing 243:16 68:7 69:2,13,13 219:12 223:13 215:18 220:10 talks 161:11 171:25 Suite 1:12 12:24 134:21 288:7 292:6 236:17 261:1 204:21 summaries 152:13 142:1 150:10 S-C 112:10 taken 1:11 4:7 5:19 tape 64:8,15,21 summarize 31:23 168:8 175:18 192:21 199:4 S-C-I-O-M-S 112:8 64:17 66:7 67:12 121:9,15 168:17 summarized 207:24 213:12 223:11 225:7 table 3:3,5 33:2 168:13 178:21 306:5 summary 48:13 228:9 236:8,9 41:8,20 42:9 43:12 45:13 46:22 184:11 186:8 168:13 178:21 306:5 43:12 45:13 46:22 43:12 45:13 46:22 226:7 283:25 168:25:13	205:22	sure 9:15 20:10,20	162:2,21 212:15		1	
suitable 218:22 81:4 112:20 240:12 284:2 236:17 261:1 204:21 summaries 152:13 142:1 150:10 S-C 112:10 taken 1:11 4:7 5:19 tape 64:8,15,21 summarize 31:23 168:8 175:18 S-C-I-O-M-S 112:8 64:17 66:7 67:12 121:9,15 168:17 summarized 233:11 207:24 213:12 T table 3:3,5 33:2 168:13 178:21 285:14,17 286:4 summary 48:13 228:9 236:8,9 39:19 40:5,18 184:11 186:8 184:11 186:8 184:11 186:8 184:11 186:8 184:11 186:8 184:11 186:8 184:24 215:23 184:24 215:23 184:24 215:23 184:24 215:23 184:24 215:23 184:24 215:23 184:25:23 184:24 215:23 184:25:23 184:25:23 184:25:23 184:25:23 184:25:23 184:25:23 184:25:23 184:25:23 184:25:23 184:25:23 184:25:23 184:25:23 184:25:23 184:25:23 226:7 283:25 184:25:23 184:25:23 226:7 283:25 226:7 283:25 226:7 283:25 226:7 283:25 226:7 283:25 226:7 283:25 226:7 283:25 226:7 283:25 226:7 283:25 226:7 283:25 226:7 283:25 226:7 283:25 226:7 283:25 226:7 283:25 226:7 283:25	suggestion 16:2	20:24 41:14 42:25	212:16 213:15			
Suite 1:12 Summaries 152:13 Summarize 31:23 32:2 33:10 Summarized 233:11 Summary 48:13 86:17 96:9 169:17 169:21 170:3 125:24 134:21 125:24 134:21 288:7 292:6 S-C 112:10 S-C-I-O-M-S 112:8 288:7 292:6 S-C 112:10 S-C-I-O-M-S 112:8 140:16 149:17 168:13 178:21	suing 243:16	68:7 69:2,13,13	219:12 223:13	215:18 220:10	1	
Summaries 31:23 142:1 150:10 S-C 112:10 taken 1:11 4:7 5:19 tape 64:8,15,21 32:2 33:10 192:21 199:4 5-C-I-O-M-S 112:8 99:12 121:11 121:9,15 168:17 233:11 207:24 213:12 223:11 225:7 140:16 149:17 285:14,17 286:4 306:5 39:19 40:5,18 184:11 186:8 184:11 186:8 184:11 186:8 86:17 96:9 169:17 243:7 244:22 43:12 45:13 46:22 194:24 215:23 194:24 215:23 169:21 170:3 246:17 248:12 246:17 248:12 25:14 10 50:25	suitable 218:22	81:4 112:20	240:12 284:2	236:17 261:1		
summaries 152:13 142:1 150:10 S-C 112:10 taken 1:11 4:7 5:19 tape 64:8,15,21 32:2 33:10 192:21 199:4 5-C-I-O-M-S 112:8 99:12 121:11 226:2,5,11 285:3 summarized 207:24 213:12 140:16 149:17 285:14,17 286:4 233:11 223:11 225:7 168:13 178:21 306:5 summary 48:13 228:9 236:8,9 184:11 186:8 184:11 186:8 86:17 96:9 169:17 243:7 244:22 43:12 45:13 46:22 194:24 215:23 194:24 215:23 194:24 215:23 194:24 215:13 169:21 170:3 246:17 248:12 246:17 248:12 25:14 10 50:25 26:7 283:25 184:21 13:20	Suite 1:12	125:24 134:21	288:7 292:6		0	
summarize 31:23 168:8 175:18 192:21 199:4 5-C-I-O-M-S 112:8 64:17 66:7 67:12 121:9,15 168:17 summarized 207:24 213:12 T table 3:3,5 33:2 168:13 178:21 285:14,17 286:4 summary 48:13 228:9 236:8,9 243:7 244:22 41:8,20 42:9 194:24 215:23 task 37:22 41:8,20 42:9 43:12 45:13 46:22 226:7 283:25 task 37:22 41:0 50:25 43:12 45:13 46:22 226:7 283:25 team 215:13	summaries 152:13	142:1 150:10	S-C 112:10			
32:2 33:10 192:21 199:4 99:12 121:11 226:2,5,11 285:3 summarized 207:24 213:12 140:16 149:17 285:14,17 286:4 233:11 223:11 225:7 168:13 178:21 306:5 summary 48:13 228:9 236:8,9 39:19 40:5,18 184:11 186:8 140:16 149:17 109:21 170:3 243:7 244:22 41:8,20 42:9 194:24 215:23 140:16 149:17 184:11 186:8	summarize 31:23	168:8 175:18	S-C-I-O-M-S 112:8	64:17 66:7 67:12	1	
summarized 207:24 213:12 Table 3:3,5 33:2 140:16 149:17 285:14,17 286:4 233:11 223:11 225:7 168:13 178:21 306:5 summary 48:13 228:9 236:8,9 39:19 40:5,18 184:11 186:8 184:11 186:8 184:11 186:8 184:24 215:23		192:21 199:4				
233:11 225:7 table 3:3,5 33:2 168:13 178:21 306:5 task 37:22 169:21 170:3 246:17 248:12 246:17 248:12 246:17 248:12 25:7 246:17 248:12 25:13 25:	summarized	207:24 213:12		l .	· · · · · · · · · · · · · · · · · · ·	
summary 48:13 228:9 236:8,9 39:19 40:5,18 184:11 186:8 task 37:22 86:17 96:9 169:17 243:7 244:22 41:8,20 42:9 194:24 215:23 taught 109:14,22 169:21 170:3 246:17 248:12 43:12 45:13 46:22 226:7 283:25 team 215:13		223:11 225:7	1 .	168:13 178:21		
86:17 96:9 169:17			1	184:11 186:8		
169:21 170:3 246:17 248:12 43:12 45:13 46:22 226:7 283:25 team 215:13		1		194:24 215:23	1 –	
54.10.50.25	1		1	226:7 283:25	team 215:13	
			54:1,9 59:25	295:22	teapot 11:20	
	2.0.2, 2.0.2					
	La constant de la con	-				

Videotaped

June 30, 2010

	1 15 7.05	41 1 1 242-2	52.2.2.0.54.4	Thomason 2:2-22
tease 65:17 113:1	testified 5:7,25	thereabouts 243:3	52:3,3,9 54:4	Thompson 2:3,23
technically 213:16	264:6 270:18	they'd 160:21	58:21 64:24 65:2	5:2,2 6:3 10:24
244:25 299:14	299:19	thick 102:23 105:4	68:2,13 81:21	11:3,23 13:4,11
technology 23:17	testify 85:22 100:10	105:8 107:18	98:21 111:24	13:14,20 14:2,10
23:19	193:12 239:22	108:7,13 115:3	112:8 123:4	14:17,23 16:24
Tecum 67:25	241:11 242:10	117:17 120:2,16	126:17 128:15	17:2 19:6 20:11
telecon 55:16	243:5,14,19	153:18	132:1,4 136:1,10	22:1,6,8 27:18
telephone 68:20	244:10 253:24	thing 11:11 22:10	142:15,16 143:21	28:7,11,15 33:8
tell 6:4,12 23:14,14	255:8 305:15	33:10 36:16 68:3	143:25 144:5,9	34:19,23 35:2,5
28:3,3,11,11	testifying 100:13	68:6 74:17 87:3	145:2 146:14	35:13 43:5 44:24
37:20 48:4 49:11	102:11 242:1	89:11 92:19 97:24	147:2 154:9	45:4 53:12,16,25
50:24 58:21 94:13	testimony 141:12	104:12 108:17	161:10 166:7	58:1 68:11,24
111:23 116:15	146:2,3 147:9	126:17 129:16	168:3,5,25 170:7	69:16,18 70:4
129:7 142:4	247:17 261:12,12	171:23 195:6	170:16 171:18,23	72:15 74:1 79:24
146:15 161:6	276:1 282:4	203:12 228:3	171:23 172:4,23	80:12 83:8 84:17
176:2 188:20	290:19 303:7	233:11,24 235:18	174:6 175:7,9	84:17 93:4 96:10
192:1 194:22	304:3 307:6	255:1 256:19	176:9,13,14,15,24	101:7 116:15,21
210:22 213:3,21	testing 102:11	258:4,6,14 260:11	177:1,3 178:8	116:24 117:2,12
218:23 228:11,13	116:4,11	299:13	180:11,13,19,20	118:20 122:7
230:11 231:25	Texas 253:22	things 10:13 17:9	180:20 182:5	126:25 128:17,24
232:1,5 235:8	text 143:14 287:8	26:9 48:21 51:8	184:22 186:10,11	129:4 130:8,18
244:6 245:3,20,20	thank 14:2 17:7	56:6 65:24 66:1	187:14,16 192:23	133:17 134:20
250:3 251:15	20:23 21:15 33:12	66:10 70:12 73:16	193:21 198:21,23	135:24 137:15
266:8,25 272:2	35:15 49:25 68:22	89:6 95:2,4	203:22 204:5,10	138:2 139:8
274:20 282:15	72:13 73:21 82:24	110:21 130:13,22	205:23 206:7	141:21 142:4
300:7	94:12 101:2	134:6 136:25	208:3,13 210:2	144:25 145:2,3,10
telling 9:18 28:14	109:12 144:21	139:15 141:24	215:5 217:8	145:17 146:2
45:25 126:7,13	149:6 153:16	151:14 152:12	219:22 221:15,21	157:1 164:23
127:4 210:18	166:11 167:25	160:7 163:22	224:10,12,17	165:10,24 166:17
212:9 239:21,23	183:4 185:9 199:6	173:23 180:13	229:14,15 232:8	166:22 168:3,8,24
283:6 291:18	233:7 247:2	205:5 210:13	232:17 234:5	170:16 171:13
tells 188:17,17	268:14 277:14	211:20 216:13	237:11,11,12	174:9 176:12
· · · · · · · · · · · · · · · · · · ·	290:1 292:10	218:1,14 220:20	242:25 254:14	179:18 180:10
tempest 11:19	1	224:19,20 225:3	256:18,19,21	185:3,7 199:8,11
tempted 123:24,25	296:2,5 297:9,10	236:25 237:21	258:5 260:10	220:5 221:25
124:1	302:8,12 305:23		270:25 275:14	227:8 240:8,18
term 83:19 97:3	305:24	241:5 248:17		251:18 254:9,14
102:15	thankful 274:3	249:16 287:12	276:1 281:2	,
termed 150:15	Thapar 38:25	288:9 305:4	284:21 285:2,23	257:14,20 262:12
terms 11:13 35:25	39:23 90:11	think 11:19 13:14	289:8 291:2,8	266:5 267:14
44:25 87:20 88:3	206:21	13:24 17:2,8 18:5	294:14,14 295:15	268:15,20,23
99:16 197:1	theoretical 136:20	20:3,15 21:17,22	295:21 296:6	271:6 274:23
203:14	theory 116:16	28:7,14 30:21	297:16 303:17	275:20 277:14,16
test 115:14 252:20	117:10	31:10 32:3 34:19	thinking 260:24	278:22,23 283:2
252:23	therapeutic 273:23	37:20 41:13 44:16	third 131:11 149:7	283:15 284:25
tested 115:22	299:9	45:24 50:8,25	181:23 200:12	285:7,12 290:2
]	

Videotaped

June 30, 2010

				Page 344
202.15 204.11 14	151.20 154.16	301:22 305:13	193:9 201:11	272:11 283:18
292:15 294:11,14	151:20 154:16	told 19:12,24 28:3	210:4 219:9	tries 112:17
294:18 296:2,5 297:18 303:20	155:10 164:12,13	30:7 73:15 80:4	236:25 245:1,2	trigger 130:15,20
	166:23 168:12,18 171:10 174:5	82:17 85:17	tracked 35:12	trouble 19:17 36:19
Thompson's 28:10			161:17 196:9	50:9 257:11,12
62:19 297:19	179:11 180:13,14	117:17 127:3 129:2 134:13	201:11 208:4,6	troubling 237:9
thought 7:11 13:5	187:21 189:5		tracker 248:11	true 11:5,6 98:14
27:19 50:23 51:15	190:1 193:13	142:5 167:14 169:6 176:6	tracker 246.11 trackers 26:25 27:2	179:17 307:8
59:9 130:21	194:16 196:24		tracking 160:11	truly 238:14 292:23
161:22 196:14	201:23 207:24	178:19 181:7,8,8 188:5 192:20	211:12 212:5	truncated 35:4
213:5 218:9	213:13 214:6,20	194:15 205:20	211.12 212.3	trust 179:3 222:13
227:17 228:4	215:22 216:2,7,18		250:10	248:6
231:22 236:6,24	216:23 219:8	221:5,13 230:6 239:21 241:10,25	tracks 211:9	trusted 218:16,20
245:1 250:4,9	226:6,12 228:9	,	trail 124:4 125:18	220:15 260:24
260:25 263:10 282:3	234:13 239:18	242:2,4,9 243:8 243:12,13,18,20	trained 115:17	295:2
	242:13 247:6,10 256:13 269:10	243:12,13,16,20	263:7,25	truth 28:4,11,14
thoughts 129:22 130:15	272:6,15 280:5,7	254:21 259:6,6	training 110:1	80:11 84:2 138:15
thousand 255:24	282:8 285:18	260:4 262:1,16	221:20 263:9	245:24 246:1
three 25:2 38:9,14	286:5 288:4 293:8	263:19 282:3	transcript 307:6	251:16 261:23,25
47:17 81:24 158:7	295:16 306:8	289:13 290:7	transcripts 38:21	268:9,12 289:13
200:16,24 255:5	timeline 12:24	291:17 293:16	49:14	290:7 291:17,18
260:12 269:16,17	71:24 81:25	299:7	transfer 138:23	293:18 294:3,25
280:8 283:24	108:15 150:17	tomorrow 295:19	153:23 155:17	303:8 305:11,14
three-page 67:2	163:15,21 233:20	tool 27:4	156:15 158:21,22	305:15
throwing 298:21	290:18	top 183:25	214:19 250:14	truthful 240:15
thumb 33:9,11,25	timely 283:3	topic 182:3 195:12	transferred 282:10	truthfully 288:21
34:24 218:24	times 40:21,22	topics 80:4 195:16	transferring 174:1	try 14:8,13 47:10
219:20	151:17 165:6	torsade 210:15	translated 36:22,24	47:10,11 50:15
time 4:14 15:4	222:8 224:6 239:3	total 140:1 162:2,6	52:10 159:19	82:1 110:7 113:1
16:20 26:22 32:9	294:12	162:7,14 170:23	translates 112:22	182:2 215:15
32:12 40:20 44:3	titled 3:11,20	196:16	transmit 206:12	240:14 243:16
50:25 53:10 54:12	today 6:10,23 7:7	totality 174:25	transmitted 206:7	245:24,25 282:25
56:2 64:16,22	8:4 16:6 23:25	totally 152:25	208:7	289:13 290:7
78:21,25 79:6,18	28:11 30:13 33:2	176:22	transparency	trying 27:23 28:20
79:21,21 80:16	37:25 67:8 69:2	Totowa 164:7	114:18	28:21,25 35:16,17
81:13 82:4 93:22	73:13,18 79:18,24	166:14 169:4,20	transparent 56:24	43:2 50:23 56:8
94:1,14 97:5 98:6	84:19 85:2,22	185:22,24 187:17	111:1,6 114:22	60:17 65:7 66:13
104:20,24 109:9	129:3 130:14	toxicity 139:21	tremendous 258:9	92:14 119:13
115:7,23 116:5	179:10,14 195:1	208:2 273:23,24	trending 70:19	121:22 132:20,22
118:18 119:5,24	209:7 221:10	274:12,21 298:6	trial 200:8 202:13	132:23 138:10
121:10,16 122:14	229:12 235:23,24	298:13,15 299:8,9	trials 97:2,3,25	140:19 151:14
128:8 131:6	236:2 240:25	to-do 20:6	196:4	157:18 170:6
132:20,24 133:3	247:18 251:6,12	track 27:3 34:5	tried 26:7 46:7 48:8	192:4 213:14
142:24 144:14	255:12 256:6	51:3,10,12 80:25	149:20 179:8	219:8,11 234:13
146:7 147:7	264:19 280:5,7	167:2 191:22	232:9,9 256:13	260:19 275:18
	<u> </u>			
L			with the second	

Videotaped

June 30, 2010

282:12,13 289:3	Uh-huh 7:3 39:15	304:24	upsetting 157:22	verbatim 10:13
290:9	47:18 107:10	understanding	up-front 241:18	12:13 34:6 35:12
Tucker 2:8,12	135:14 148:11	68:13 69:20 80:3	use 6:18,19 27:15	49:14 162:12
turn 89:23 159:5	206:22 252:25	103:17 122:4	60:9 63:15 65:19	208:4 298:25
186:22	264:22	132:3 147:16	66:14 74:19 83:18	verification 109:11
turns 177:24	unable 18:18 22:16	157:12 198:8,9,10	92:21 96:23 97:2	verified 108:3
TV 125:2	22:19 73:24	198:15 201:19	123:5 136:22	109:10
twice 19:13 28:1	162:17 272:24	222:22,25 275:10	220:4 272:2	verify 12:5 32:13
30:7 44:18 60:9	unauthorized	287:9	useful 90:7 222:15	77:15 109:8 152:7
two 3:11 6:10 7:17	34:15	understood 18:3	usual 87:3 161:5	208:25 284:9
8:5,6 9:12 10:5	unaware 165:4	62:22 232:15	usually 27:3,13	verifying 54:12
12:1,5 15:8 20:17	190:16	undertake 56:9	61:3 74:12 89:21	version 140:7
24:9 28:16 30:2	unbeknownst	undetected 143:16	162:20 223:13	versus 119:5 136:2
30:13,25 31:16	115:13	unequivocally	uttered 225:18	viable 222:16
32:3 33:9,9 37:24	uncertainty 271:23	229:20	U.S 72:22 73:3	video 2:19 4:4,4 5:4
40:7,17 54:2	uncomfortable	unethical 225:5	148:18,20 149:4,5	64:13,13,19,20
58:24 70:12 71:12	80:19 176:7	238:22	155:17 156:10,15	67:24 77:21
80:4 81:24 93:8,9	unconscionable	unexpected 179:22	156:16 157:14	104:18,18,22,23
93:24 94:19 95:18	224:25 225:5	unexplained	175:6 189:16	121:7,7,13,14
107:4 110:25	uncover 68:16	178:15	194:23 210:5	168:10,10,15,16
111:6 139:17	uncovered 171:19	unhook 39:20	211:21 231:4	183:3 215:20,20
140:1 142:22	221:4	uniformity 117:5	274:10	215:25 216:1
143:11 151:14	underlying 72:19	unit 162:18		226:3,3,9,10
158:7 170:4	72:19 82:18 122:1	United 1:1 4:8		247:4,4,8,9 285:4
181:23 187:19,21	156:6 160:4	148:16 149:2	valid 139:14	285:15 286:2
202:17 205:7	167:15 174:6	214:1 272:20	validated 120:18	306:1,3,4
207:19 214:7	235:10 298:3	unknown 158:6	validity 302:6	videographer 4:15
225:18 227:10	undermine 303:15	unmodified 287:21	valuable 136:1	videotape 4:6 121:4
229:4 250:4 255:5	underreporting	unnecessary	value 290:25	285:16 286:3
260:12 272:8	140:5	259:21	Valued 204:12,20	videotaped 1:10
279:16 280:16	understand 6:12,22	unreported 143:1	205:17 207:18,21	306:6
two-year 27:8	19:20 69:1 80:6	182:9,13 185:15	208:5	view 26:11 80:9,10
154:13	84:22 86:2,20,22	186:2 188:25	variability 275:10	257:16
type 51:5,20 52:18	121:18,21,25	189:14 191:4,12	variable 130:3	viewed 83:1,2,3
62:7 133:21	122:3 125:5,23	191:18 193:1	variation 32:15	vigorous 81:19,20
140:18 161:14	154:22,25 155:1	287:6	variety 298:9	301:6
220:13	157:6 169:17	unsolicited 275:12	various 34:20	vindicate 296:23
typically 66:10	177:12 202:2	untrue 291:15	198:7 199:16	vindicated 294:21
86:12 88:24	213:12 223:19	unusual 86:25	254:5	294:23
111:11 114:10	243:4,23,24,25	185:17	vast 86:14	violate 25:9
211:4,9 215:15	244:1,1,2 252:24	update 95:14	verbal 6:14 156:21	violation 270:12
246:11 248:18	253:6 261:2,7,13	updated 95:8,17	157:15 231:3,15	violations 160:3
	261:14,18 263:15	updating 95:11	287:10	Virginia 1:1 4:10
U	268:16 282:24	Uppsala 88:22	verbally 6:20	253:20 255:21
UDL 70:25 116:2	283:22 304:13,23	upset 92:12	115:24	virtue 275:3,7
		•		
X		-		

Videotaped

June 30, 2010

			· · · · · · · · · · · · · · · · · · ·	Page 340
1100 11	177 05 170 11 10		15.15 10.4 05.17	20.7 67.22 77.22
visual 120:11	177:25 178:11,12	warnings 95:22	15:15 18:4 25:17	28:7 67:22 77:23 124:11 153:18
269:19	181:20,25 189:5,8	Washington 62:17	25:22 29:22 31:9	124:11 153:18 168:5,21 191:9
vis-a-vis 101:5	189:24 199:12	88:20 102:25	49:2,15 73:15	•
273:2	211:1 213:11	175:7	74:6 90:25 91:23	192:23 238:17
vitae 30:1	227:12 228:2,9,21	wasn't 60:4,22 68:8	115:22 122:9	294:15 300:20
voice 48:7	234:21 237:22	112:19 160:6	142:20 147:2,7	whatsoever 230:5
void 136:19 141:7	238:4,17 242:22	165:9 171:4 189:1	175:12 198:7	WHI 202:13
volumes 7:8,17	247:18 248:12,13	192:12 205:12	201:14 203:1	white 7:10 29:8
17:22	249:19 254:16	235:14 236:8,9	204:3 206:11	34:4 46:7,17,24
voluntary 274:9,10	255:1 256:3,19	249:13 251:6	207:15 218:8	51:24 52:7 105:20
292:7	258:3 259:1,9,11	270:24 272:12	219:13 220:18	138:12,13,14,17
volunteered 63:5	260:11,14 261:2	284:16	244:25 246:24	147:19 159:15,15
vulnerabilities	281:18 289:6	waste 118:17	272:8 273:12	161:25 164:9
27:10 174:13	290:10 291:14	watch 125:2	297:21	174:12 217:20
217:20 246:13	292:12,19 294:21	way 14:7 22:17	weren't 33:22	244:21
vulnerability	294:21,23 295:4	55:9 56:14 109:13	239:21 244:22	whoever's 296:20
289:19	295:19 296:9,11	131:11 133:10	288:9	who've 61:1
vulnerable 83:24	296:13 297:14	136:17 138:22	West 1:1 2:8,12	Williams 2:19 4:15
177:21	302:21 303:6,11	143:9 149:24	4:10 253:20	willing 69:9 146:20
	303:14,15,25	186:1 187:5 188:8	255:21	190:9 229:11
	304:1,5,5,6,13	189:2,13 195:14	we'll 7:1 14:10	237:15 239:14
wait 128:12 149:25	305:9,10,17	220:11 222:2,16	21:23 43:7,8	251:14 254:8
165:15 285:9	wanted 8:20 20:20	227:5 230:19	44:21 45:12 64:8	256;4 259:24
292:15	20:21 25:8 49:17	238:8,13 260:9	65:1 69:17 79:24	289:20
waiting 135:15,16	51:2,9,16 52:8	270:20 291:8	177:10	win 59:4
135:17	53:8 56:21 82:22	295:4 296:14	we're 4:4 8:11	window 151:24
walk 64:10 251:14	124:20 141:2	ways 142:22 143:12	10:22 13:8 17:3	wisdom 210:25
253:16,23	147:13 197:2	191:15	19:10 20:15 27:25	259:20
want 6:19 9:15	214:15 223:11	weather 6:23	28:1 37:24 39:8	wise 302:22 303:5
10:11 12:8 17:8	225:6 236:15	web 124:1,22	39:18 40:4 43:11	wish 50:11 224:15
18:8 19:22 20:10	239:16 241:3,13	126:12,22 134:17	47:1,10,22 64:19	244:3,8
20:24,25 21:12	248:20 249:7	135:9 146:10	93:12 104:22	wishes 114:23
23:14 29:1 32:11	254:18 293:25	251:10 287:21	121:13 127:17	withdraw 257:8
32:17 33:24 39:20	294:17 304:11	Wednesday 1:13	143:13 145:15	258:6,7,15 260:3
40:8 42:25 45:3	wants 13:15,16	4:13 43:25	146:1 176:19	withdrawal 210:14
54:7 56:18 62:18	145:13 228:5	week 15:3 78:24	186:10,11 215:25	257:18 287:13
62:19 73:11 75:15	warned 23:24	145:22	245:24 246:8	withdrawals 25:15
81:4,10,10 86:1	160:2,13 196:16	weeks 17:22 42:14	247:8 271:3	85:7,7
89:6,25,25 92:1	warning 48:10 49:7	260:13	277:11 282:25	withheld 145:20,21
93:11 94:13	66:15 99:2,13	weigh 304:12	285:1,2 286:2	withholding 50:22
110:25 111:19	159:7,9 160:8	weight 234:16	290:8 291:3	witness 5:5 7:22
115:2 130:5 131:9	161:4,10 163:4	238:10 296:25	294:14 295:5	11:25 13:13,19
140:17 143:8	165:2,14 166:15	welcome 35:6	302:16 303:23	14:1 16:10 17:1,5
148:9 168:1,2,7	171:3,11 174:20	went 7:9,10 8:9,18	304:21	27:2 28:17 33:17
175:1,21 177:11	278:18,25 279:5	8:19,20 12:14,18	we've 8:23 12:10	34:22 35:1,3,6
		-		

Videotaped

June 30, 2010

38:11,17 41:4	303:21 304:7,14	112:2 222:11	XUS 113:3 193:22	14 149:18
49:10 52:23 54:23	305:21 306:9	workshops 109:25	194:11,13,25	14th 150:20
55:25 56:3,7,10	307:1	workup 95:20		15 15:15 163:5
56:23 58:3,7 59:7	witnessed 222:3	worried 175:13	<u> </u>	182:17,20,21
64:12 65:13 69:22	witnesses 18:15	219:25 294:16	yeah 10:24 11:3	183:13,14,14
70:11 73:1 79:14	23:5 137:2 226:19	worry 280:9 293:19	28:7 35:24 36:14	184:1 185:7
80:16 83:1 84:14	255:25	worrying 130:13	39:11 45:16,23	186:23 194:5,17
84:16 94:9 96:11	wondered 208:22	worse 298:11	150:9 157:16	250:18 283:9
101:8 107:2 112:9	wondering 251:5	worth 263:4	176:24 237:11	15th 135:11 165:13
112:11 116:8	251:13	wouldn't 137:21	249:20 256:2	218:3 243:1,2
117:3,13 118:21	word 123:5 146:14	156:22	264:20	247:25 250:8
125:16 127:1	158:2 210:2	wrapped 209:18	year 118:24 278:21	266:21 278:18,25
128:20 134:22	219:23 220:4	write 8:1 17:23	years 12:22 16:23	15-day 18:21 76:3
135:25 138:3	227:3	32:12 50:9 52:18	18:25 86:10 94:19	172:3,5
141:22 144:11	worded 132:5	64:3 81:8 196:4	147:6 220:7 272:8	18 3:4 41:21 53:23
156:23 157:2	wording 142:2	220:8 222:18	yesterday 8:5 12:16	18th 203:21,22
164:1 165:12	171:24 218:20	236:16 239:19		206:6,13,13
166:1,24 168:25	219:16,16,20	writing 25:1 49:13	\$	208:23,25 209:17
170:18 174:10	223:10	49:21 115:25	\$150 78:20	233:10
176:13 179:19	words 6:19 118:3	196:4 227:5 243:3	0	1818 1:12 4:12
180:4,11 193:24	129:6 141:25	written 20:3 137:1		1968 1:6
194:1 199:3,7	143:8 176:9	182:14 194:9	03 150:20,20	1992 26:11
208:1 213:14	225:17 282:15	200:3 206:12	07 216:23	
220:6,12,14	283:4 304:25	217:22 218:4	08 216:23	2
227:24 232:11,13	work 16:22 23:3	223:8 228:6	1	2 64:21 121:9
233:3 237:16	33:17 34:16 55:21	229:21 245:9	139:9,10,22,23	129:11 131:10
238:7,15,18	55:25 56:3,10,13	wrong 146:21	64:15 151:3	265:14 278:17
239:14,17 240:9	56:24 59:2,15	147:15 166:23,23	152:22	2nd 43:25 50:6
240:12 241:1,3	60:21,25 61:20	227:12 228:22	132.22 1st 158:5,22 187:4	62:8 65:9 92:8
242:1 244:12,18	65:12 66:13 70:20	237:19 245:4	212:3 276:6	154:4 177:7 225:8
245:7 251:19	79:4 83:19 88:8	255:2 256:20	1:00 44:2	242:15
252:10 253:24	89:20 98:4 112:21	258:17,22 259:2	1:05 121:12,16	2:06 168:12,13
254:10,16 257:17	123:21 136:2,3	259:11,17 260:11	10:27 64:16,17	2:16 168:14,18
257:19 258:12	146:22 220:10	260:15 262:6	10:43 64:18,22	20 105:23 275:14
259:10 261:23	238:19 241:14,19	295:4 296:22	11 3:5,15 9:24	275:22 278:9,13
266:6 267:15	254:18,19 255:4	wrongdoing 260:18	12:10 42:9 43:10	20th 184:10,19,21
270:20 274:17	256:24 292:25	261:17 293:20	53:24	187:17 199:4
277:15 278:1	worked 33:16	304:21	11th 150:20	279:23
282:7 283:8,23	78:23,24 79:7	wrote 20:2 95:16	11:38 104:20	2000 182:21 187:2
286:6 288:20	86:9 98:23 99:1	150:10 158:9	11:40 104:24	2001 108:24 149:16
290:6,10,19	109:19 122:15	196:6 219:1,2	1150 2:9	2003 151:24 152:23
291:22 292:12,17	133:14 211:3		12 44:2	171:20 173:23
292:24 294:4,8,13	220:9 228:23	X	12/1/04 106:17	2004 62:17 91:6,8
294:16,19 296:3	254:5 263:6,24	X 18:25,25 103:23	12/1/2004 276:10	91:10 102:23
296:25 302:23	working 27:12 57:3	103:24,24	12:03 121:10,12	103:12 104:13

Videotaped

June 30, 2010

				1 age 340
105:2,8,19 106:14	2009 58:17 124:15	261 3:19 70:3 71:14	130:8 131:7 138:7	9:20,24 12:10,11
105.2,0,17 100.14	134:17	72:7,11 148:1	138:12 141:7	49:21,24 72:10
109:1,2,2 119:8	2010 1:14 4:13 59:3	209:24 250:2,5,19	145:1 251:9	120:9 143:15
150:6 153:18	135:11 250:18	251:1,17 254:2	264:19 267:23	50-hour 79:3
235:17 267:4	283:9 306:7	282:4,6,10,22	268:11,25 284:22	505 (b) 130:1
276:6,12	21 182:21 183:11	283:7	285:24	515 2:13
2005 153:21 154:12	183:13,21 184:1	268 2:23		53 3:11
161:22 284:5	187:11 188:1	28 2:4 66:21 67:14	4	55 3:12
2006 66:21 67:15	278:9 279:9	204:20 205:25	4 148:5 168:17	58 3:14
143:3 147:2,8	281:19,21	233:6 234:6	226:5 278:17,18	59 3:15
150:12,14 156:4	21st 185:24	28th 159:24 203:16	4:23 247:6	
163:5 171:19,20	213-430-3378 2:14	203:21 204:13	4:24 247:10	6
171:25 175:11,14	216-696-2137 2:10	207:21 278:19	40 8:11	6 106:19 147:2
175:15,17 178:7	220 77:24 78:12	279:1,4,4	40-hour 79:3	209:23,25 286:4
178:13,17 180:14	206:18	28208 204:17	42nd 2:13	306:5
182:10 185:16	24 3:8	207:24,25	44115-1475 2:10	6th 165:16 166:6
188:10 189:15	247 2:22	28213 201:18	45 3:3,5	272:7
191:10 193:8	25 153:23 201:20	286 2:23	47 3:6,8,9	6/15/2010 3:21
214:5 216:9 234:7	202:4 203:13	29 53:22,24	482 106:11	6:00 15:13
267:4 272:7	204:18 205:23	29464 2:4	483 98:24 99:7,8	6:30 15:11
278:25 279:1,2,25	208:8	297 2:24	100:5 113:14	60 3:16,18
281:10,22 284:6	25th 166:2 185:24		157:23 159:8	60-hour 79:3,4,14
2007 164:7 166:12	201:15 203:23,23	3	166:15 174:20	62 183:7 187:10
170:14 174:19	203:25 206:8,11	3 121:15 164:7	183:15 184:2,4,7	192:24 193:25
176:4 191:2,6,11	206:23 207:6,14	166:12 174:19	184:15,21 279:4	64108 2:17
193:4,13 195:4	208:24 209:8	183:25 191:2,11	279:22	65400 67:4
216:19,21 233:22	273:4,6,8	193:3 195:4	483 s 13:2 73:7	65402 67:4
259:16	250 3:3 41:13,16	216:19,21 250:22	99:18,22 150:19	69 3:19
2008 66:19 82:9	45:14 53:23 54:10	251:1 282:5	161:4 165:2	7
92:12 103:13,15	54:15 59:25	3.4 120:12	167:19 171:3,6	
103:17 142:24	251 3:5 43:11 45:20	3:19 215:22,23	484 115:10	7 149:18
147:1,3,5 161:20	46:22 53:23 54:10	3:30 215:24 216:2	49 8:8,12	7:30 15:10
173:11 175:3,14	252 3:6 48:3 51:25	3:46 226:6,7		70 9:2,2
175:16 178:5,15	253 3:8 49:11,20	3:50 226:8	5	8
180:14,18 182:1	254 3:9 50:1	3:52 226:12	5 2:22 159:5,6,11	8 183:14 185:7
182:21 183:11,21	255 2:16 3:11 53:21	30 1:14 4:13	159:12 165:1	186:14 188:21
184:1,21 187:11	54:1,8,15	30th 306:7	181:21 187:23	8th 159:24 171:25
192:13 193:17	256 3:12 55:7	30-day 233:20	226:11 233:9	8th 159:24 171:23
211:18 218:11	257 3:14 58:11	302 2:24	282:18 283:24	816-474-6550 2:17
228:16 232:25	258 3:15 59:19	35 78:24	285:17	843-216-9118 2:5
233:2 234:18	259 3:16 60:16	350 113:18,23	5:11 285:18	87 163:24 165:4
235:4,20 248:23	26th 165:18 207:3	350 s 113:21	5:15 286:5	168:20 171:9
248:25 249:2	207:4	3500 110:15 113:4	5:30 15:10	172:11 173:17,19
273:5 279:23	260 3:18 65:3	37 201:2,7	5:39 306:8,10	174:3 176:21,23
281:23 284:12	2600 1:13	38 124:13 128:23	50 8:8,23 9:2,7,19	191:3 280:5
201.23 207.12				191.3 400.3
	·	•		X-13